Newport Medical Instruments, Inc.

Newport Breeze E150 Ventilator

Operating Instructions

OPR150 Rev. D
02/08

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INTRODUCTION

The Newport Breeze E150 Ventilator is intended for use by properly trained and qualified persons. It is restricted for use by and upon the direction of a physician. Before attempting to use this device in an actual life-support situation, the operating personnel must become practiced in the function and the effect of the various controls.

Please review this manual thoroughly and operate the device in simulated situations before dedicated use.

The Newport Breeze E150 Ventilator, being a life support device, requires the clinician to be functionally familiar with its clinical application. It is recommended, therefore, that the initial introduction, set-up and in-service training be performed by an authorized Newport Medical Instruments representative.

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GENERAL DESCRIPTION

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The Newport Breeze E150 is a general purpose ventilator which is used for ventilatory support of neonates, pediatrics or adults.

The ventilator is provided with an Air/Oxygen Mixer to control the F_IO_2. Controls are provided for the operator to select the function of the ventilator, a transducer monitors peak, mean and baseline pressures, and alarm systems are built-in to alert the clinician to violations of preset limits.

The Breeze E150 is classified as an electronically controlled, pneumatically powered ventilator with intermittent spontaneous flow (I.S.F.). It functions as a volume controlled, time cycled, constant flow, or a pressure controlled, time cycled, constant flow ventilator.

The Breeze Operates In Six Basic Modes:

VOLUME CONTROL
- A/C (Assist/Control) + SIGH
- A/C
- SIMV (Spontaneous Intermittent Mandatory Ventilation)
- SPONT (Spontaneous)

PRESSURE CONTROL
- SPONT
- SIMV
- A/C

Primary Controls Allow Operator To Select:

- MODE
- PRESET (Indicates mechanical ventilation settings while in Spont Mode)
- F_IO_2
- RATE
- INSP TIME

Primary Controls Allow Operator To Select:

- FLOW (Mechanical)
- PEEP/CPAP
- TRIGGER LEVEL
- PIP (Pressure Control Vent.)
- PRESSURE (PEAK, MEAN, BASE)
- ALARM LOUDNESS
-  (Alarm Silence)
- NEB (Nebulizer Source) ON/OFF
- MANUAL (Manual Breath)
- ON/OFF (Power)
- Pressure RELIEF VALVE (Pop-off)
- APNEA ALARM DELAY (or LOW CPAP)
- HI PRESS ALARM
- LO PRESS ALARM
- SPONT FLOW

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SPECIFICATIONS

MODES

VOLUME CONTROL
- A/C + SIGH
- A/C
- SIMV
- SPONT

PRESSURE CONTROL
- SPONT
- SIMV
- A/C

CONTROLS

F_IO_2:	.21 - 1.0 $\pm$ 3 O2%
FLOW:	3 - 120 L/min
INSP TIME:	.1 - 3.0 seconds
RATE:	1 - 150 bpm
V_T (Tidal Volume):	10 - 2000 + ml
PIP (Peak Inspiratory Pressure):	0 - 60 cmH_2O
PEEP/CPAP:	0 - 60 cmH_2O
SPONT FLOW:	0 - 50+ L/min
TRIGGER LEVEL:	-10 - +60 cmH_2O
Maximum Inverse I:E:	4:1 (Insp. Time: Exp. Time)
Pressure RELIEF VALVE:	0 - 120 cmH_2O
Electronic Pressure Gauge:	-10 - +120 cmH_2O
Internal Battery:	60 minutes

ALARMS

Audible and Visual

HI PRESS:	10 - 120 cmH_2O
LO PRESS:	3 - 99 cmH_2O
APNEA:	5, 10, 15, 30, 60 seconds
LOW CPAP:	0 - 60 cmH_2O
Low Battery :	15 min. operating time remaining

Audible Only

Gas Supply Source Failure
Power Failure

Specifications

Alarm Silence 60 seconds

INDICATORS

EFFORT (Inspiratory)
HI PRESS ALARM
LO PRESS ALARM
APNEA
Low Battery
Alarm Silence
Battery In Use

SUMMARY OF DISPLAYS

F_IO_2
FLOW (Mechanical)
SPONT FLOW
INSP TIME
RATE (Mechanical)
TOTAL RATE
V_T (Tidal Volume)
TRIGGER LEVEL
EXP TIME
I:E Ratio
PRESSURE
- PEAK Pressure
- MEAN Pressure
- BASE Pressure

Alarm Panel
- Battery In Use
- Low Battery
- APNEA
- LO PRESS
- HI PRESS
- Alarm Silence

POWER REQUIREMENTS

AC Power 100, 120, 220, 240 VAC (± 10%)
47 - 63 Hz, 45 Watts max.

Battery Power The sealed, lead acid, internal battery will power the Breeze E150 for 1 hour minimum when fully charged. It features automatic recharge.

Gas Requirements

Oxygen:	35 - 90 psig (50 ± 10 nominal)
Air:	35 - 90 psig (50 ± 10 nominal)

Dimension and Weight

Height:	10 inches	(25 cm)
Depth:	11 inches	(28 cm)
Width:	13 inches	(33 cm)
Weight:	30 lbs	(13.6 kg)
Ship Weight:	64 lbs	(29 kg)

Agency Requirements Designed to meet applicable requirements of CSA 22.2
IEC 601-1, IEC 601-1-2 EMC, MDD Directive 93/42/EEC

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ASSEMBLY & SET UP PROCEDURES

Assembly

The clinician can assemble the equipment without assistance by implementing the following instructions:

Remove Operating Manual and warranty card (process per instructions) from the shipping container. Remove all parts/assemblies from the container and inspect each for completeness and verify there is no shipping damage.

The complete assembly consists of the following parts:

Quantity	Description
1 each	Newport Breeze E150 Ventilator with watertrap for high pressure air inlet
1 each	Base
1 each	Pole (two pieces plus nut and retaining washer)
5 each	Casters

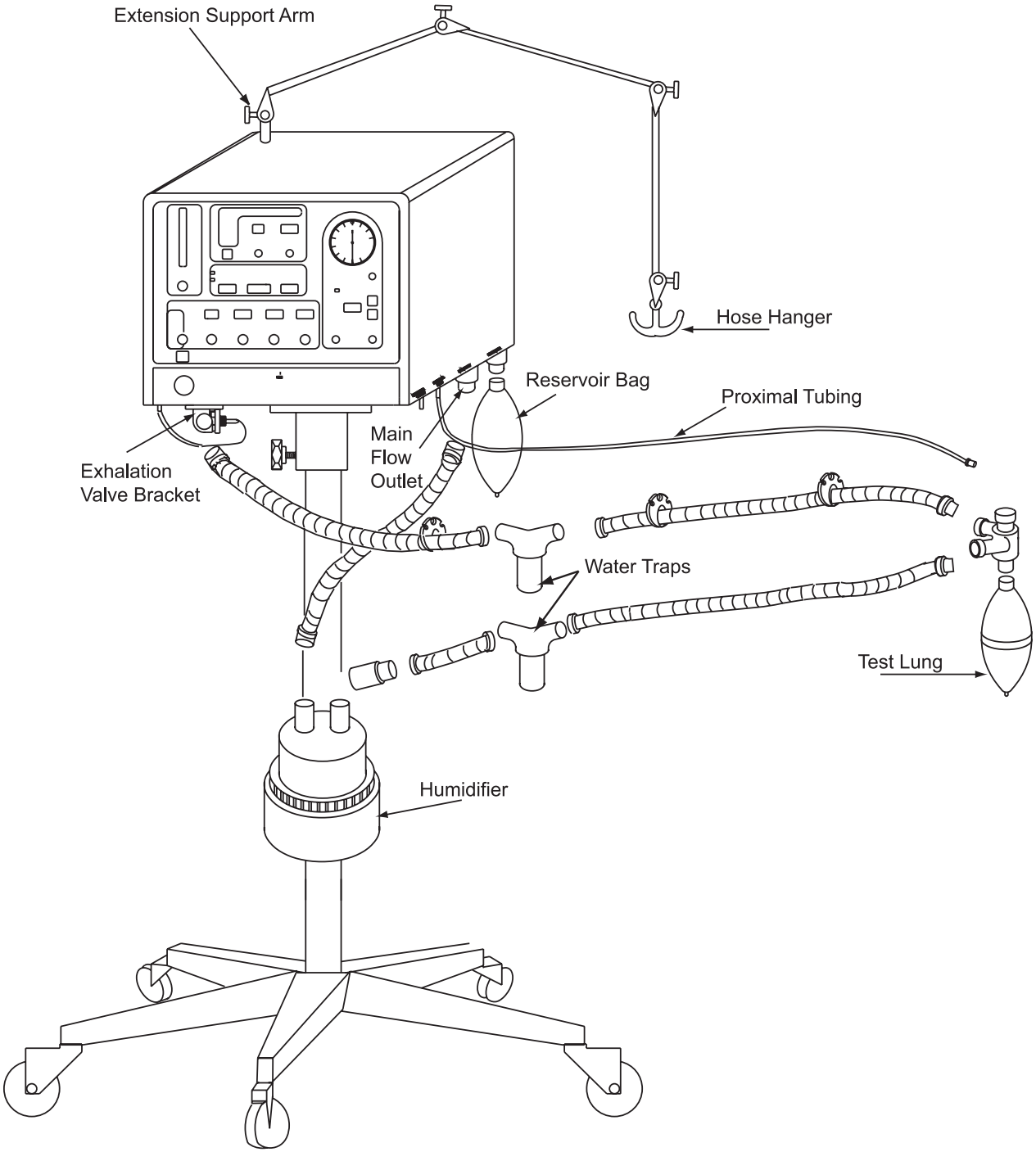
NOTE: Pole, base and casters included in standard assembly for shipments outside the U.S.A. only.

1 each	Oxygen Supply High Pressure Hose (10 ft.)
1 each	Air Supply High Pressure Hose (10 ft.)
1 each	2 liter Reservoir Bag
1 each	Adjustable Pressure Relief Valve (0-120 cmH_2O)
1 each	Extension Arm
1 each	Patient Circuit Tubing Holder
1 each	Exhalation Valve with Mounting Bracket
1 each	Reservoir Bag Cap (OPTIONAL USE ONLY)
1 each	Operating Manual
1 each	Service Manual

Set up Procedure

1. Assemble Pole Stand.
   a. Insert a caster in each of the five base sockets.
   b. Connect two pole lengths together and insert tapered end tightly into base socket. Secure pole to base with washer and nut.
   c. Mount ventilator on pole and secure by tightening the knurled knob on pole mount adapter.
2. Attach the 2 liter Reservoir Bag to the bottom opening of the Reservoir Bag Adapter.
3. Insert the Pressure Relief Valve (pop-off) into the rear panel.
4. Connect and secure the High Pressure Air Hose to the water trap's DISS fitting on the rear of the ventilator.
5. Connect and secure the High Pressure Oxygen Hose to the DISS fitting on the back of the ventilator.
6. Insert the Extension Arm into the socket located on top of the ventilator and secure by turning the wing-nut clockwise. Attach the Patient Circuit Tubing Holder in the clamp at the end of the Extension Arm.
7. Attach the Exhalation Valve Bracket to the bottom of the ventilator (located left front) with the two thumb screws provided. Snap the Exhalation Valve assembly into the black plastic clip with the inlet connector facing the front of the ventilator. Attach the exhalation tubing on the Valve to the EXP OUTLET connector on side panel.
8. Connect the inspiratory limb of the patient breathing circuit to the MAINFLOW OUTLET and connect the proximal pressure sensing line of the circuit to the PROXIMAL PRESSURE INLET beneath the right side of the ventilator.
9. Attach the end of the expiratory limb of the breathing circuit to the Exhalation Valve.
10. A chain with a small ring on the end is used to attach the Reservoir Bag Cap to the back panel of the Breeze E150. Remove a hex-nut screw from the lower left rear panel of the Breeze E150 and re-install it through the small ring at the end of the chain. This enables the Reservoir Bag Cap to hang from the chain beside the Reservoir Bag opening.

NOTE: The Reservoir Bag Cap is ONLY used to cap off the Reservoir Bag opening when patient-triggered ventilation of very small or very weak patients (Spont. insp. efforts of less than $-1 cmH_2O$) is attempted. For ventilation of patients with spontaneous inspiratory efforts of $-1\ cmH_2O$ or greater, the Reservoir Bag should ALWAYS be in place and the opening should NEVER be capped off. See pg. 4-1.


Extension Support Arm
Hose Hanger
Reservoir Bag
Proximal Tubing
Main
Flow
Outlet
Exhalation
Valve Bracket
Water Traps
Test Lung
Humidifier

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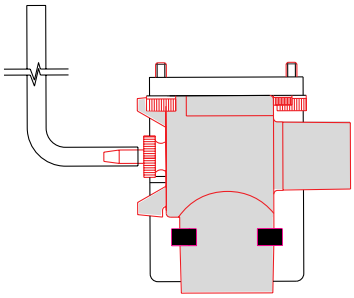
ACCESSORIES

Exhalation Valve (Standard Accessory)



EXHALATION VALVE

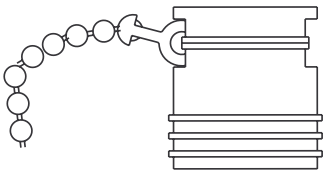
One permanent Exhalation Valve is included with the Breeze E150. It is designed to be used for neonate, pediatric and adult patients.

Exhaled volumes can be measured at the patient circuit wye or from the exhaust port of the Exhalation Valve with a respirometer or an equivalent independent volume measuring device.

NOTE: If volumes are measured at the Exhalation Valve exhaust port, spontaneous flow may cause the volume measuring device to read higher volumes than are actually being delivered. Accurate volumes may be measured at the proximal wye connector.

The Exhalation Valve assembly can be autoclaved, pasteurized, gas sterilized or cleaned using most cleaning/disinfectant type solutions, such as Cidex.

Reservoir Bag Cap (Standard Accessory Optional Use Only)



RESERVOIR BAG CAP

A Reservoir Bag Cap MAY be used to cap off the Reservoir Bag opening in special circumstances.

WARNING Capping off the Reservoir Bag Outlet with the Reservoir Bag Cap removes the gas reservoir from the inspiratory limb of the breathing circuit. This should ONLY be done when attempting patient-triggered ventilation on very small or very weak patients (Spont. insp. efforts less than -1 cmH_2O) who cannot adequately lower the pressure at the proximal airway to trigger the Breeze E150 to deliver a mechanical breath with the Reservoir Bag in place. SPONT FLOW is maintained at the set level.

Ensure that the patient is being carefully observed when the Reservoir Bag Cap is in use.

WARNING The Reservoir Bag Cap should NEVER be used in place of a Reservoir Bag if the patient is capable of drawing a negative pressure of -1 cmH_2O or greater with appropriately set Spontaneous Flow and the Reservoir Bag in place. If the patient IS capable of drawing a negative pressure and the Reservoir Bag has been replaced with the Cap, the patient will be able to open the Emergency Intake and draw in ambient gas when their spontaneous inspiratory flowrate exceeds the set SPONT FLOW.

Heated Humidifier (Optional Accessory)

A heated humidifier or heat moisture exchanger should be used whenever continuous ventilatory support is instituted. The Fisher & Paykel heated humidifier may be ordered with the Breeze E150. For heated humidifier specifications, operation and application, refer to the humidifier manufacturer's operation manual. For heat moisture exchanger instructions, refer to manufacturer's instructions.

The humidifier chamber should be filled with sterile water to an appropriate level per manufacturer's instructions and the heater unit plugged into an A.C. outlet prior to switching ON.

Evaluate the humidifier's internal resistance to spontaneous inhalation. In the event of a total source gas failure, the patient must overcome this resistance in order to obtain ambient air through the ventilator Emergency Intake Valve.

Caution Remember to turn the humidifier "OFF" after switching the Breeze E150 "OFF".

Breathing Circuits (Optional Accessory)

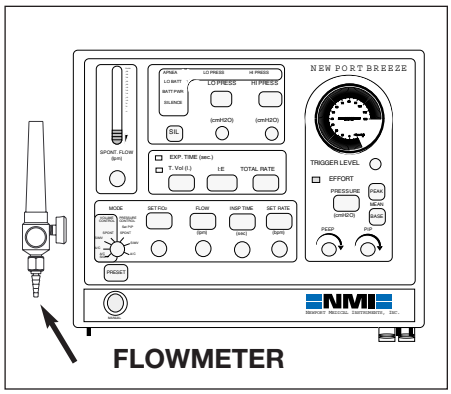
The Breeze E150 is guaranteed to perform within specifications when the NMI permanent breathing circuit and the NMI Exhalation Valve are utilized.

The NMI permanent patient breathing circuit is available in neonatal-pediatric bore or adult bore.

The Newport Breeze E150 accommodates the use of different types of breathing circuits which might incorporate a heated humidifier with or without heated wires and/or a nebulizer. Read and implement the manufacturers' instructions for assembly, decontamination, or sterilization of such equipment.

If you intend to use a circuit other than the NMI permanent breathing circuit, contact NMI for information regarding the need for special adapters.

Auxiliary Flowmeter (Optional Accessory)

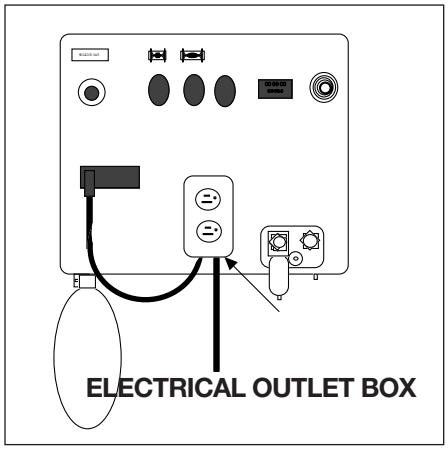


An optional 28 psi AUXILIARY FLOWMETER is available to attach to the left side of the Breeze E150. This allows you to deliver a calibrated flow of mixed gas which is at the same F_IO_2 as the F_IO_2 setting on the Breeze E150 face panel. The AUXILIARY FLOWMETER operates separately from all other ventilator functions.

The AUXILIARY FLOWMETER may be used to supply mixed gas to a resuscitation bag, a continuous nebulizer, etc. Since the outlet supplies gas at 28 psi, only the NMI flowmeter or similar flowmeter which has been calibrated at 28 psi should be attached to this outlet. If a flowmeter which has been calibrated to 50 psi is used, the flow which is actually delivered may be different from that which is indicated.

WARNING If the AUXILIARY FLOWMETER is set above 15 L/min and the main flow is set above 60 L/min, accuracy of the main flow setting may be affected.

Auxiliary Electrical Outlet Box (Optional Accessory)



An optional AUXILIARY ELECTRICAL OUTLET BOX may be attached to the back panel of the Breeze for the convenience of plugging in accessory equipment such as humidifiers and monitors.

Caution Only medical grade equipment with a similar power consumption and current rating as the ventilator should be connected to the Auxiliary Electrical Outlet Box.

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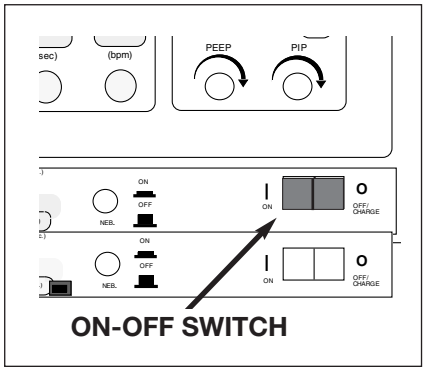
DESCRIPTION OF CONTROLS, DISPLAYS AND INDICATORS

ON-OFF Switch



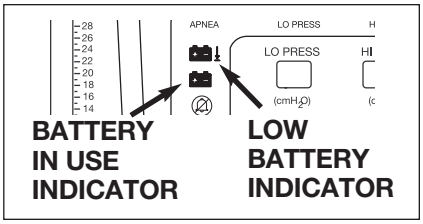
The ON-OFF SWITCH is located on the front of the ventilator behind the door at the base of the face panel. It provides electrical power for electronically controlled ventilator functions and activates the electric power failure alarm system.

When the ventilator is plugged into an A.C. outlet the internal battery charges.

When switched ON, a temporary audible alarm sounds and all lights on the front panel light up for two seconds. This indicates a functional system (self-testing).

All electronically operated ventilator functions are deactivated when the power switch is in the OFF position.

Internal Battery



The Breeze E150 has an internal battery which will maintain full ventilator function for approximately 60 minutes when fully charged. It will automatically power the ventilator in the case of A.C. power disconnect or power outage. An audible alarm sounds every five minutes to indicate the internal battery is in use. Additionally, a quick pulse alarm indicates that approximately 15 minutes of battery power remains.

Fuse Holder

A 1 Ampere, 250 V fuse (for 100-120 Volt) or .5 Ampere, 250 V fuse (for 220-240 Volt) protects the ventilator's electronic system. Use only these specified fuses to replace blown fuses. Consistently blown fuses may indicate that service is required. Contact your NMI authorized representative.

Compressed Air High Pressure Hose

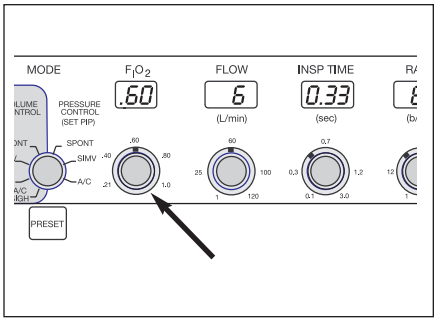
The 50 psig Air High Pressure Hose is connected to the DISS air inlet on the water filter trap located on the rear of the ventilator. The water filter trap should be monitored frequently for condensation and is drained by pushing UPWARD on the metal pin in the bottom of the bowl.

Oxygen High Pressure Hose

The 50 psig Oxygen High Pressure Hose is connected to the smaller DISS female connector on the back of the ventilator.

NOTE: Ensure that both oxygen and compressed air supply sources are clean and dry.

Air/Oxygen Mixer



Accuracy:	± 3 O_2%
Nominal Supply Pressures:	40 - 60 psig
Accuracy:	± 5 O_2%
Operating Supply Pressures:	35 - 90 psig

The Air/Oxygen Mixer is a two stage precision pressure regulation and proportioning device. It is designed to accurately mix medical air and oxygen to any selected F_IO_2 between .21 and 1.0 for delivery through the ventilator to the patient. Compressed air and oxygen sources are connected to the standard DISS fittings on the rear of the Air/Oxygen Mixer.

F_IO_2 accuracy is ± 3 O_2% of the control setting with gas supply pressures of 40 - 60 psig. With gas supply pressures of 35 - 90 psig, F_IO_2 accuracy is ± 5 O_2% of the control setting.

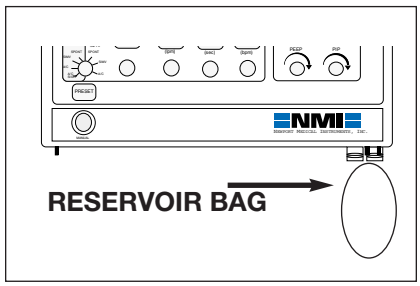
If one gas supply source is lost, a pneumatic crossover valve opens, allowing the ventilator to continue to operate. When the crossover valve opens, the reed alarm on the rear of the Air/Oxygen Mixer activates, alerting the clinician to the gas supply pressure failure.

WARNING Should inlet gas supply fail, immediately provide an alternate form of ventilation until the gas supply is re-established. Although the ventilator will continue to function if one gas supply source is lost, the oxygen percentage will change.

WARNING In the case of total inlet gas failure the patient will receive no breaths from the ventilator. The emergency intake valve inside the ventilator will allow the patient to breathe ambient air. Opening pressure is approx. - 4 cmH_20.

As with any other type of gas mixing apparatus, an oxygen analyzer, preferably with high and low alarm limits, is recommended to ascertain that the desired F_IO_2 is being delivered.

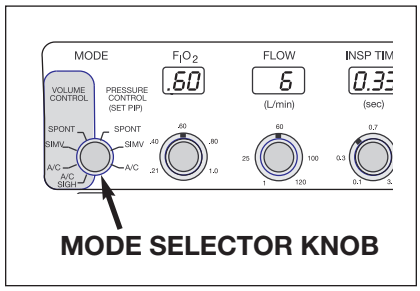
Reservoir Bag



A two-liter bag connected to the Reservoir Bag Outlet functions as a reservoir of selected oxygen concentration for the SPONT FLOW.

NOTE: The two liter Reservoir Bag may be replaced with a one or three liter Reservoir Bag, as needed, to meet patient ventilation demands. You may also replace the Reservoir Bag with the Reservoir Bag Cap when necessary to enhance patient triggering in very small or weak patients (Spont. insp. efforts less than -1 cmH_2O). See pg. 4-1 for guidelines and warnings for use of the Reservoir Bag Cap.

Mode Selector Knob



The MODE Selector Knob allows the operator to select between the Volume Control Modes which include: A/C + Sigh, A/C, SIMV, and SPONT; and the Pressure Control Modes which include: SPONT, SIMV, and A/C.

WARNING Ensure the safety of your patient by checking the appropriateness of all ventilator settings prior to switching between Pressure Control and Volume Control Modes of Ventilation.

Volume Control Modes

In A/C (Assist/Control), a positive pressure breath is delivered in response to each patient inspiratory effort (that reaches the Trigger Level). Tidal Volume is determined by the FLOW and INSP TIME settings and is digitally displayed as V_T in the Data Display Panel.

NOTE: If the patient does not trigger, the Breeze E150 automatically delivers breaths according to the RATE control setting.

A/C + Sigh (Assist/Control plus Sigh) functions much like A/C with the addition of a mechanical “Sigh” breath equal to 1.5 times the volume of the preset tidal volume (1.5 times the inspiratory time) delivered to the patient every 100 breaths.

In SIMV, the patient may breathe spontaneously from the ventilator’s spontaneous flow and receive a fixed number of mandatory positive pressure breaths. Tidal volume of the mandatory breaths is determined by the FLOW and INSP TIME settings and is digitally displayed as V_T in the Data Display Panel. The number of mandatory breaths is controlled by the RATE setting and synchronized with the patient’s breathing pattern by the TRIGGER LEVEL setting. The patient’s spontaneous breaths are drawn from the SPONT FLOW through the circuit and Reservoir Bag which has the same F_IO_2 as the mandatory breaths.

NOTE: For more information on SIMV, see section titled SIMV WINDOW pg. 5-5.

In the SPONT mode, the patient breathes exclusively from the spontaneous flow and Reservoir Bag at the selected F_IO_2. The patient has complete control over each breath with respect to rate, tidal volume and peak flowrate. CPAP may be added.

Manual breaths deliver flow according to the FLOW control setting. The Breeze E150 will cycle to exhalation when the MANUAL Breath button is released, or after 2 seconds, or if the peak inspiratory pressure of the Manual Inflation reaches the HI PRESS Alarm setting. If the peak pressure reaches the Pressure RELIEF VALVE setting the peak pressure will plateau there for a maximum of 2 seconds or until the button is released.

Pressure Control Modes

In A/C (Assist/Control), a positive pressure breath is delivered with each inspiratory effort (that meets the TRIGGER LEVEL) by the patient. The INSP TIME control determines the length of the mechanical breath and the peak gas flow delivered to the patient is at the flowrate chosen on the FLOW control. Peak pressure is determined by the PIP setting. Expiratory Time is digitally displayed in place of V_T in the Data Display Panel.

NOTE: If the patient does not trigger, the Breeze E150 automatically delivers breaths according to the RATE control setting.

In SIMV, the patient may breathe spontaneously from the ventilator's SPONT FLOW and receive a fixed number of mandatory positive pressure breaths. As with A/C, the INSP TIME control determines the length of the mechanical breath and the peak gas flow delivered to the patient is at the flowrate chosen on the FLOW control. The maximum Peak Pressure of each mandatory breath is determined by the PIP setting. Expiratory Time is displayed digitally in place of V_T in the Data Display Panel. The number of mandatory breaths is determined by the RATE control and synchronized with the patient's breathing pattern by the TRIGGER LEVEL setting. The patient's spontaneous breaths are drawn from the SPONT FLOW through the circuit and Reservoir Bag. SPONT FLOW has the same F_IO_2 as the mandatory breaths.

NOTE: For more information on SIMV, see section titled SIMV WINDOW pg. 5-5.

In the SPONT mode, the patient breathes exclusively from the SPONT FLOW and ventilator Reservoir Bag at the selected F_IO_2. The patient has complete control over each breath with respect to rate, tidal volume and peak flowrate. CPAP may be added.

Manual breaths delivered in this mode will be pressure limited at the PIP setting and/or the Pressure RELIEF VALVE. The breath will cycle to exhalation when the MANUAL button is released or after 2 seconds or if the HI PRESS Alarm limit is reached.

SIMV Window (Volume or Pressure Control)

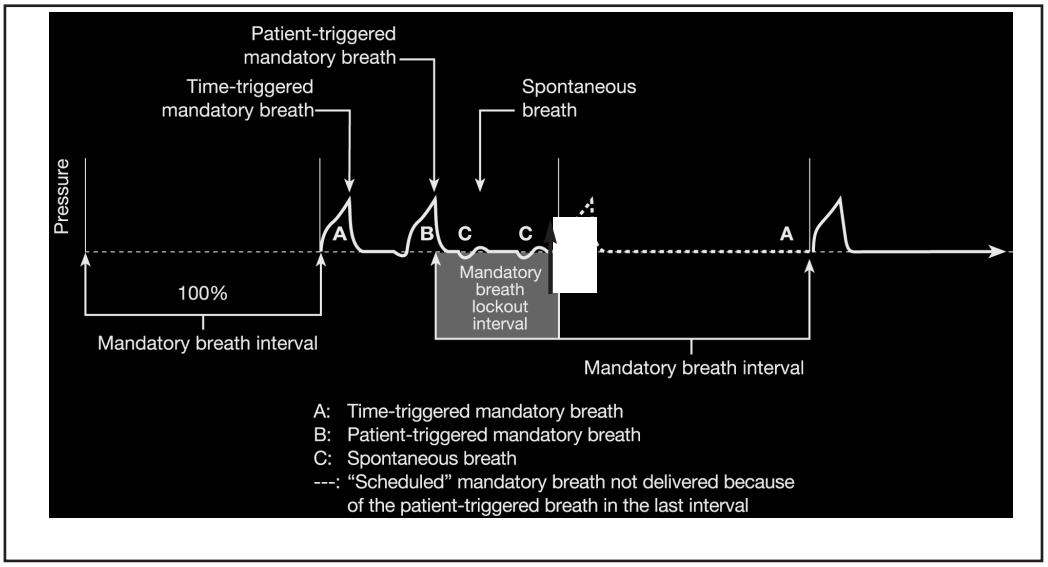
There are three types of breaths available in SIMV: VIM (ventilator initiated mandatory), PIM (patient initiated mandatory), and SPONT breaths. The RATE control determines the total number of mandatory breaths (VIM or PIM) delivered each minute. The total number of mandatory breaths equals the total number of mandatory breath intervals each minute. Dividing the RATE setting (b/min) into 60 (seconds) results in the duration of each mandatory breath interval.

The 100% SIMV window allows for patient triggers throughout the entire mandatory breath interval. In order to minimize problems of synchrony with spontaneous and PIM or VIM breaths, the first breath the patient triggers in any mandatory breath interval is the PIM breath. The patient has the rest of the interval to breathe spontaneously. If the patient stops triggering breaths, and one complete mandatory breath interval has elapsed without any type of breath occurring, a VIM breath will be delivered.

The following diagram identifies the three different SIMV breath types as A, B, and C, and the way they interact within the 100% SIMV window. In the first mandatory breath interval, neither a VIM or a PIM breath has occurred, therefore at the beginning of the next interval a VIM (A) breath will be delivered. During the second mandatory breath interval following the VIM (A) breath, the patient triggers a PIM (B) breath, *(remember that the first breath the patient triggers in any interval is a PIM (B) breath).* The patient may breathe spontaneously (C) throughout the rest of the interval. In the third mandatory breath interval, the normally scheduled VIM (A) breath is not delivered because the patient received a PIM (B) breath in the second interval. In the fourth mandatory breath interval, since one complete interval has elapsed without any type of breath occurring, a VIM (A) breath is delivered.

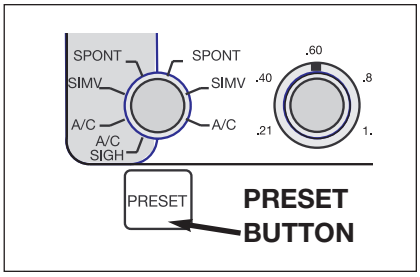
A mandatory breath lockout interval is activated whenever the patient triggers a PIM breath. This limits the number of mandatory breaths (VIM or PIM) the patient receives in 60 seconds, to the RATE setting (b/min). In the diagram, the lockout interval begins at the end of inspiration of the PIM (B) breath in the second mandatory breath interval until the start of the third interval. The VIM breath is not delivered at the start of the third mandatory breath interval because a PIM breath was triggered in the last interval. The patient can breathe spontaneously throughout the mandatory breath lockout interval.

100% SIMV Window diagram



AWNRNI GhT ePSNO TLFWOs iwct hna/droF OLMWTEREm su tebt ruen do“”ni nISVMa dnS OPTNm doset orpvodi eag for patient spontaneous breathing.

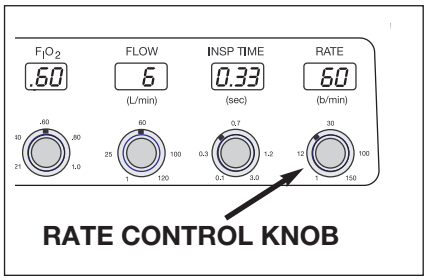
Preset



Push PRESET in the SPONT mode to light the digital displays prior to a mode change to verify that the ventilator's controls are set at a safe level for the patient.

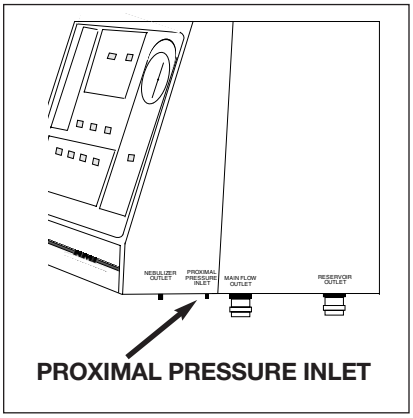
The PRESET condition displays Expiratory Time in the Data Display Panel when the PRESSURE CONTROL SPONT Mode is chosen and it displays V_T in the Data Display Panel when the VOLUME CONTROL SPONT Mode is chosen.

Rate Control (b/min)



The RATE control is adjustable in one breath per minute increments from 1 to 150 breaths per minute. Mandatory breaths are available to the patient in all mechanical modes. In the SPONT mode, respiratory rate is determined by the patient.

Proximal Sensing Inlet



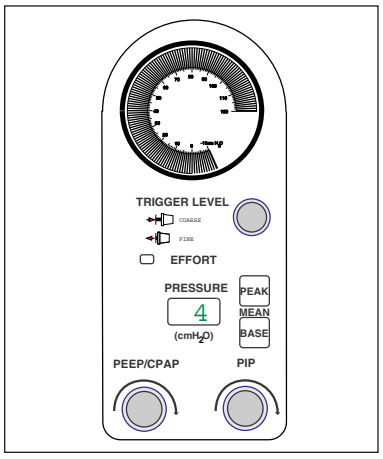
The Electronic Pressure Gauge and PRESSURE Display reveal pressure sensed through the small bore proximal pressure sensing line. This small bore portion of the patient circuit attaches to the PROXIMAL PRESSURE INLET on the lower right side of the ventilator.

A purge flow of gas discourages water or contaminants from entering the ventilator through this port. It is also advisable to install a hydrophobic bacteria filter between the PROXIMAL PRESSURE INLET and the small bore tubing to further protect the internal components of the Breeze E150 from contamination.

Electronic Pressure Gauge Principle of Operation

The Electronic Pressure Gauge has an operating range of -10 to +120 cmH_2O, and each cmH_2O has its own LCD (Liquid Crystal Display) cell.

Understanding the Display



The electronic pressure gauge displays the peak pressure of the last breath, baseline pressure (PEEP/CPAP), pressure rise and fall during inspiration and exhalation, patient trigger level, and patient effort (trigger).

1. **Peak Pressure Indicator:** The LCD cell that corresponds to the peak pressure of the last breath illuminates (non-flashing green) until the next inspiration has taken place and a new peak pressure has been established.

2. **Baseline Pressure Indicator:** All LCD cells from a baseline pressure of zero to the PEEP/CPAP level illuminate (non-flashing green), indicating the current baseline pressure.

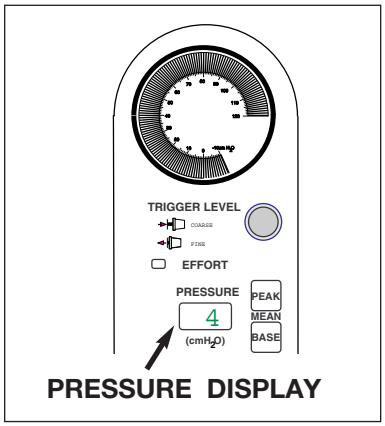
3. **Inspiration and Exhalation:** Starting at the baseline pressure indicator, all LCD cells illuminate (non-flashing green) up to the peak pressure (inspiration), then return to a “dark” condition as pressure returns to the baseline level (exhalation).

4. **Patient Trigger Level:** The patient trigger level LCD cell is illuminated (non-flashing green) to indicate the level of effort the patient must achieve in order to trigger a breath. If pressure becomes more negative than the set patient trigger level, or if the patient trigger level is set higher than the baseline pressure indicator (PEEP/CPAP), the patient trigger LCD cell will begin to flash (intermittent green) until this condition no longer exists.

5. **Patient Effort:** With a baseline pressure of zero, patient effort will be displayed in LCD cells -1 to -10 cmH_2O. The LCD cells equal to the effort generated by the patient will illuminate (non-flashing green). With a PEEP/CPAP level set, the LCD cells illuminate (non-flashing green) to indicate the elevated baseline pressure level. The "lit" LCD cells displaying the PEEP/CPAP level will turn off (go dark) as effort is generated by the patient to trigger the ventilator.

NOTE: When the baseline pressure is elevated and the patient trigger level is set equal to the baseline level, the LCD indicator for both will remain dark.

Pressure Display



PRESSURE DISPLAY

The PRESSURE Display provides a continuous readout of MEAN Airway Pressure (MAP) as monitored by the built-in pressure transducer through the PROXIMAL PRESSURE INLET. PEAK or BASE(line) Pressure readings can be displayed for 30 seconds by depressing either button. The display returns to MEAN Airway Pressure after 30 seconds or when PRESET is pushed.

In the Mechanical Modes, the PEAK Pressure display is updated at the onset of the inspiratory phase of each mechanical or manual breath. It displays the maximum airway pressure sensed during the previous mechanical inspiratory phase.

In the SPONT Mode, the PEAK Pressure display is updated with each patient Trigger, or at the onset of a second Manual Inflation.

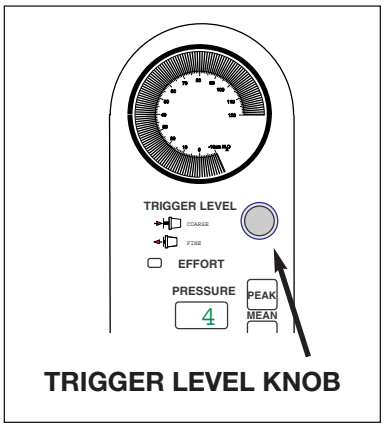
Pressure is sensed at the airway 100 times per second (negative and positive pressure are sensed). Every time a patient trigger or mechanical inspiration occurs, an average of Mean Pressure is calculated. The MEAN Airway Pressure display is updated every patient triggered or mechanical breath. It displays the average MEAN Airway Pressure of the four previous mechanical breaths or trigger conditions.

In all mechanical modes of ventilation, the BASE Pressure reading is updated at the onset of each mechanical inspiration or every 3 seconds (whichever is shorter) to display the Baseline Pressure sensed during the previous expiratory phase or spontaneous breathing period.

In the SPONT mode, the BASE Pressure reading is updated every three seconds.

Trigger Level

Principle of Operation



TRIGGER LEVEL KNOB

The TRIGGER LEVEL knob adjusts the amount of effort (negative pressure) the patient must exert to initiate (trigger) a breath. Patient effort is displayed in cmH_2O, and measured through the proximal pressure line with a pressure transducer inside the ventilator. The patient trigger level indicator is displayed on the electronic pressure gauge. The TRIGGER LEVEL knob has two adjustment positions, COARSE and FINE. To adjust the trigger level in the COARSE position, pull out on the TRIGGER LEVEL knob, clicking it into position. To adjust the trigger level in the FINE position, push in on the TRIGGER LEVEL knob, clicking it into position. The trigger level can be adjusted from -10 to +60 cmH_2O in the COARSE position. In the FINE position, there is a maximum adjustment of 5 cmH_2O above and below the current trigger level setting. Rotate clockwise to increase the effort needed to trigger a breath, and counter-clockwise to decrease the effort.

NOTE: The trigger level setting is not baseline (PEEP/CPAP) compensated.

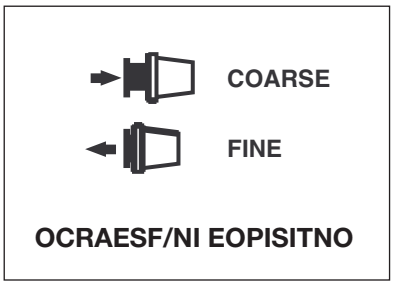
WARNING Any time a change is made to the baseline, the trigger level should be readjusted.

Understanding the Display

The electronic pressure gauge is similar in function and display as a standard pressure gauge. It displays the peak pressure of the last breath, baseline pressure (PEEP/CPAP), pressure rise and fall during inspiration and exhalation, patient trigger level, and patient effort (trigger). Instead of a pointer reflecting the pressure changes, each cmH_2O has its own Liquid Crystal Display (LCD) cell that illuminates (non-flashing green) when energized. Starting at the baseline pressure indicator, all LCD's illuminate (non-flashing green) up to the peak pressure (inspiration), then return to a "dark" condition as pressure returns to the baseline level (exhalation). All LCD cells from a baseline pressure of zero to the PEEP/CPAP level will be illuminated (non-flashing green). If the baseline pressure is zero, the LCD cells equal to the effort generated by the patient will illuminate (non-flashing green) below the baseline level. The patient trigger level LCD will be illuminated (non-flashing green) to indicate what level of effort the patient must achieve in order to trigger a breath.

If an LCD cell is already energized and receives another input to "turn on", it will go dark (turn off) instead. For instance, if PEEP is set at 5 cmH_2O and the patient trigger level is set at -2 cmH_2O, LCD cells 0,+1, +2, +4, and +5 will be illuminated. LCD cell +3 will be dark (turned off) to indicate the -2 cmH_2O Trigger Level. As the patient creates the -2 cmH_2O effort to trigger a breath, LCD cells +5 and +4 will go dark until the ventilator responds with a positive pressure breath.

Setting the Trigger Level



The COARSE adjustment on the TRIGGER LEVEL knob is to bring the trigger level within 5 cmH_2O of the desired setting. To adjust in the COARSE position, pull out on the TRIGGER LEVEL knob, clicking it into position. Rotate the knob clockwise to increase the patient effort, counter-clockwise to decrease patient effort. Once you are in the desired range, push in on the knob, clicking it into the FINE position. Rotate the knob to achieve minimal patient effort without causing the ventilator to self-trigger.

Although it appears you are adjusting the trigger level 1 cmH_2O at a time, you are actually adjusting the trigger incrementally within the current cmH_2O ("lit" LCD) setting. If the trigger level is adjusted equal to or greater than the baseline pressure, the trigger level LCD cell will begin to flash (green). If the trigger level is adjusted within the LCD cells illuminated to reflect the PEEP/CPAP level, the LCD cell indicating the trigger level will go dark (turn off). If the baseline pressure is zero and the trigger level is adjusted below baseline, the trigger level LCD cell will illuminate (non-flashing green).

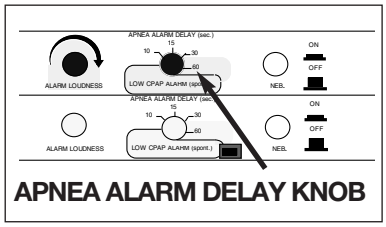
Readjustment of the trigger level is necessary any time a change in the baseline pressure occurs. The "triggering" or "sensing" of a patient effort is indicated by the "EFFORT" LED flashing on and off (orange). If you are having difficulty sensing the patient effort (EFFORT LED not lighting), and the trigger level is set to the "least amount of effort", you may want to decrease the SPONT FLOW setting. You are probably using more flow than the patient needs. You may also want to consider substituting the Reservoir Bag Cap in place of the Reservoir Bag (Note: See section titled Reservoir Bag Cap on pg. 4-1). If you see the patient generate significant negative pressures beyond the set trigger level, you may want to increase the SPONT FLOW setting.

NOTE: If the TRIGGER LEVEL knob is in the COARSE position (pulled OUT) upon "power ON", the trigger level will be set between -10 to +60 cmH_2O, depending on the rotation of the TRIGGER LEVEL knob. If the knob is in the FINE position (pushed IN) upon "power ON", the trigger level will be set between -10 to -5 cmH_2O, depending on the rotation of the TRIGGER LEVEL knob.

Patient Effort Indicator

The EFFORT LED will "blink", orange, on and off with each patient effort that meets the TRIGGER LEVEL knob setting. If the EFFORT LED is not "blinking" with each patient effort, adjustment of the TRIGGER LEVEL knob and/or the SPONT FLOW level may be necessary.

Apnea Alarm/ Low CPAP Alarm

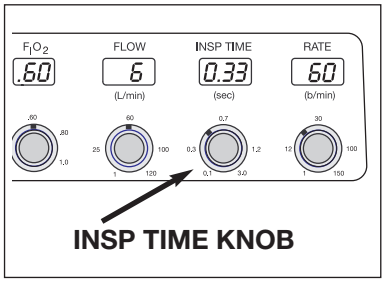


APNEA ALARM DELAY KNOB

The APNEA ALARM DELAY knob is located behind the door on the lower portion of the face panel. This alarm receives its input from the TRIGGER LEVEL Sensor. In mechanically assisted modes, the APNEA ALARM DELAY may be set for 5 (indicated as LOW CPAP), 10, 15, 30, and 60 seconds. If no patient effort or mechanical breath is sensed for the set delay time, the alarm sounds.

In the SPONT Mode, the LOW CPAP ALARM is available. When the knob is set in the first position (LOW CPAP), the LO PRESS Alarm is activated to detect a drop in baseline pressure or disconnect and the TRIGGER LEVEL Sensor no longer monitors spontaneous efforts. If the Baseline Pressure (CPAP) drops below the LO PRESS Alarm setting for more than 4 seconds, the alarm sounds.

Inspiratory Time



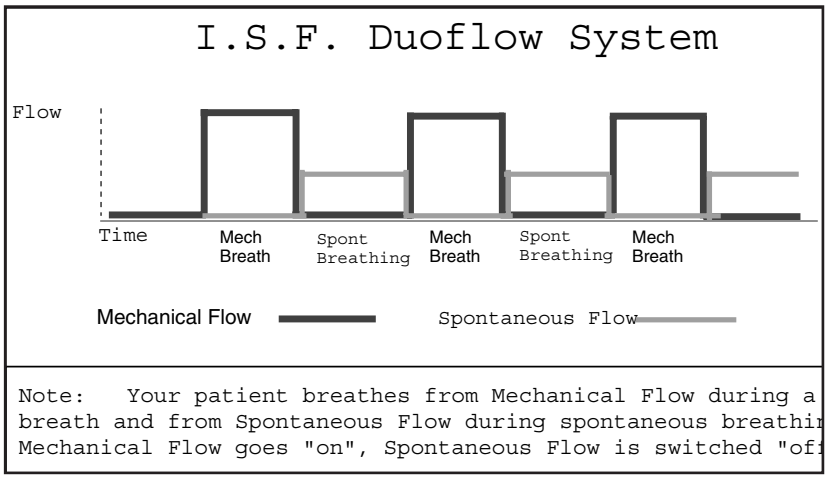
INSP TIME KNOB

Inspiratory Time (INSP TIME) is adjustable from 0.1 to 3.0 seconds. It is graduated in increments of 0.01 second from .1 to 1 second and in increments of .1 second from 1 second to 3 seconds.

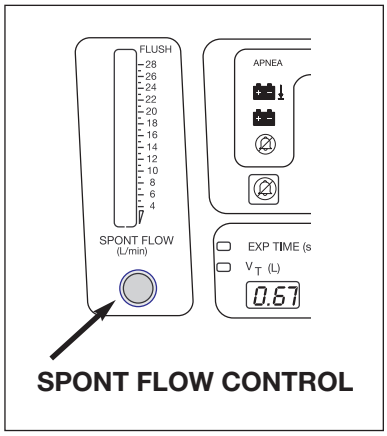
When the selected time is reached, the inspiratory phase is terminated and the Breeze E150 cycles into the expiratory phase. The colon (:) in the INSP TIME display flashes whenever an inverse I:E ratio is set to be delivered. The entire INSP TIME display flashes when it is set to exceed the maximum inverse I:E ratio. The maximum inverse I:E ratio that may be delivered is 4:1.

Duoflow (Mechanical Flow/ Spontaneous Flow)

The Duoflow system allows you to control Mechanical Flow (FLOW) and Spontaneous Flow (SPONT FLOW) separately. Mechanical Flow is delivered to the patient during mechanical breaths only and Spontaneous Flow is directed through the patient circuit in-between mechanical breaths.



Spontaneous Flow



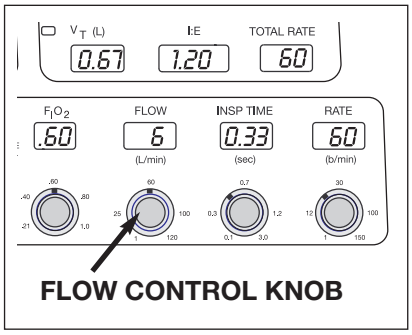
The SPONT FLOW is calibrated from the minimum position to 28 L/min. When the knob is turned fully clockwise the SPONT FLOW will deliver approximately 50 + L/min. Set the SPONT FLOW to meet patient spontaneous inspiratory demands during spontaneous breathing in the SIMV and SPONT modes of ventilation. If patient effort exceeds the set SPONT FLOW, the patient may draw mixed gas from the Reservoir Bag.

If the Electronic Pressure Gauge displays a significant negative pressure swing during patient inspiration, increase the SPONT FLOW. If on exhalation, the Electronic Pressure Gauge displays a significant positive pressure swing, lower the SPONT FLOW setting.

In SIMV and SPONT Modes, the SPONT FLOW should always be adjusted to meet patient spontaneous inspiratory flow demands. In A/C, set SPONT FLOW at 4 L/min and adjust as needed to stabilize PEEP/CPAP (Baseline) levels.

NOTE: SPONT FLOW provides a source of gas for spontaneous breathing in the unlikely event of an electronic ventilator malfunction.

(Mechanical) Flow

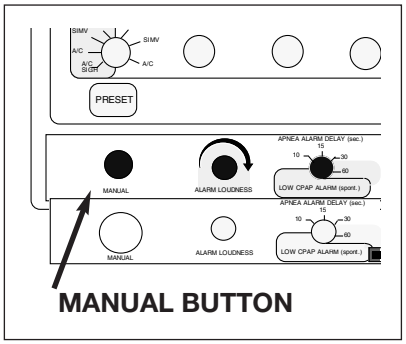


FLOW may be adjusted in 1 L/min increments from 3 -120 L/min. This setting determines the flowrate delivered to the patient during a mandatory or manual breath.

Mandatory tidal volume (V_T) is a product of the mechanical FLOW (L/min) and the INSP TIME (seconds). In the VOLUME CONTROL MODES, V_T is digitally displayed in the Data Display Panel above the FLOW and F_IO_2 displays.

NOTE: Although digital displays may be capable of indicating tidal volumes below 30 mL, the accuracy is guaranteed above 30 mL only.

Manual Inflation



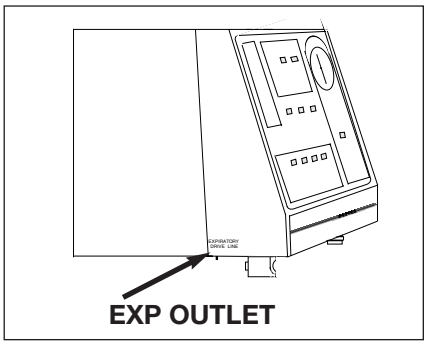
The MANUAL Button allows you to give your patient positive pressure inflations in any mode. Depressing the button causes the Breeze E150 to deliver gas to the patient for a maximum of two seconds. MANUAL is disabled during a mechanical inspiration. The maximum number of manual inflations is 150 per minute.

In the PRESSURE CONTROL Modes, the peak pressure of the manual inflation will be limited at the PIP level.

All manual inflations cycle to exhalation if the HI PRESS Alarm limit is reached or after two seconds. If the peak pressure reaches the Pressure RELIEF VALVE setting, the pressure will plateau.

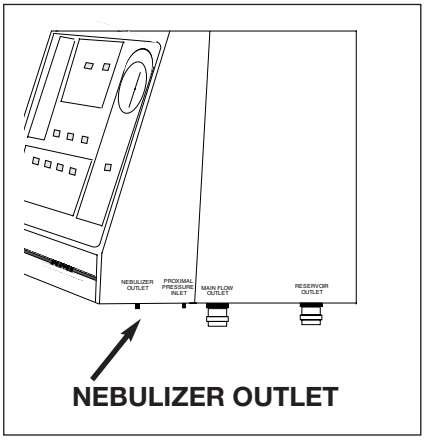
In all Modes, FLOW and F_IO_2 of the manual inflation are delivered as set, and INSP TIME and RATE are determined by the operator.

Expiratory Drive Line Outlet



The Expiratory Drive Line Outlet (EXP OUTLET) delivers pressure to the mushroom diaphragm of the Exhalation Valve during mandatory breaths and PEEP/CPAP.

Nebulizer Outlet



When connected to a nebulizer, which is placed inline with the ventilator circuit, the NEBULIZER OUTLET allows for delivery of aerosolized medications during mechanical ventilation.

The nebulizer gas source is activated with the button (NEB) located behind the door on the lower section of the face of the ventilator. Nebulization occurs during the inspiratory phase of mechanical breaths only. Gas delivered through the NEBULIZER OUTLET has the same F_IO_2 as the main flow of gas.

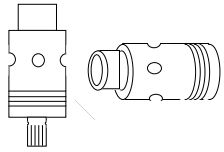
The NEBULIZER OUTLET delivers approximately 6 L/min. This flow is not part of the set FLOW. It is *additional to* the set FLOW.

NOTE: In VOLUME CONTROL Modes, the volume of gas delivered through the NEBULIZER OUTLET is automatically added into the displayed Tidal Volume (V_T).

In order to guarantee the delivery of medication through the NEBULIZER OUTLET when Inspiratory Times of less than .4 sec. are chosen, you may wish to utilize the AUXILIARY FLOWMETER in place of the built-in NEBULIZER OUTLET for powering the nebulizer.

WARNING Flow added via external Flowmeter will cause a change in delivered V_T and/or pressure waveform. The V_T change will not be reflected on the Breeze E150 face panel. Decrease mandatory flow by the L/min value added via the flowmeter, in order to maintain a consistent V_T.

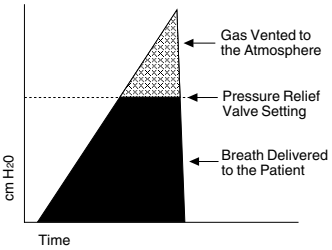
Pressure Relief Valve



PRESSURE RELIEF VALVE

The Pressure RELIEF VALVE is located in the upper left corner of the rear panel of the Breeze E150. It determines the maximum pressure that can be reached in the patient circuit during spontaneous, mandatory, and manual ventilation. This safety valve can be adjusted from 0 -120 cmH_2O. Clockwise rotation of the blue knurled knob increases and counterclockwise rotation decreases the maximum pressure (pop-off) setting. It is located on the inspiratory limb of the internal ventilator circuitry.

The Pressure RELIEF VALVE should be set above the HI PRESS Alarm setting as a safety pop-off.



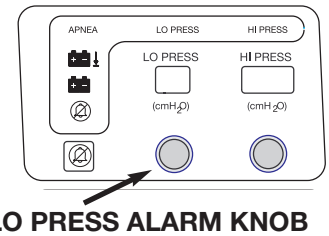
Volume Controlled Ventilation: Pressure Relief Valve Set Too Low

NOTE: If the Pressure RELIEF VALVE is not adjusted above the pressure required to deliver set tidal volume, part of the volume will be vented to the atmosphere when the relief pressure is reached.

The Pressure RELIEF VALVE is factory preset at 0.

THE ALARM SYSTEM

Low Pressure Alarm



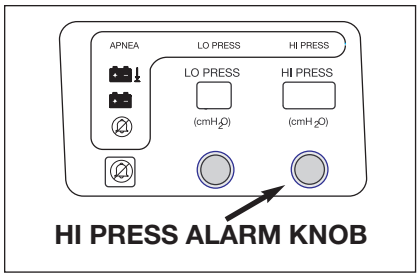
LO PRESS ALARM KNOB

The LO PRESS Alarm is active during mandatory volume or pressure controlled breaths. Also, in the SPONT MODE, the APNEA DELAY may be placed in the LOW CPAP ALARM position in order to utilize the LO PRESS Alarm as a disconnect alarm. The HI PRESS Alarm Limit is active in all modes.

In mechanical modes, adjust the LO PRESS Alarm and the HI PRESS Alarm settings so that they bracket the Peak Inspiratory Pressure (PIP) as closely as is practical. Setting the alarms within 5 cmH_2O of the Peak Inspiratory Pressure will provide the best method of detecting leaks or occlusions in the patient breathing circuit.

The LO PRESS Alarm is activated if the pressure in the patient circuit does not rise above the LO PRESS Alarm setting during the inspiratory time of a mandatory breath, or if the LOW CPAP ALARM is activated and the CPAP pressure drops below the set LO PRESS Alarm Limit for 4 seconds. This could be caused by system leaks, patient disconnect, improved patient compliance, increased patient inspiratory flow demand or accidental changes of ventilation settings. When the alarm is no longer violated, the alarm indicator “latches” (stays lit). Press the ALARM SILENCE Button to cancel “latched” alarm indicators.

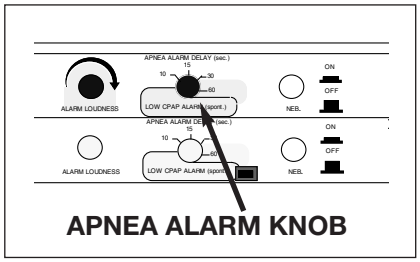
High Pressure Alarm



The HI PRESS Alarm is activated if the pressure in the patient circuit reaches the High Pressure Alarm Limit. Possible causes include decreased patient compliance, coughing, increased resistance, partial or complete blockage of the patient circuit, or accidental changes of ventilator settings.

Inspiration is terminated (Breeze E150 cycles to exhalation) when the HI PRESS Alarm is violated. When the alarm is no longer violated, the alarm indicator “latches” (stays lit). Press the ALARM SILENCE Button to cancel “latched” alarm indicators.

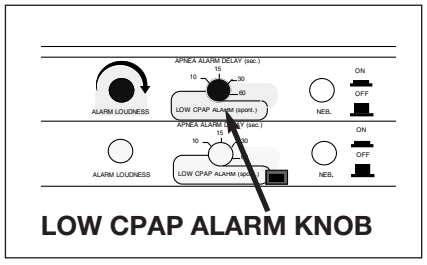
Apnea Alarm



The APNEA Alarm monitors patient mechanical and spontaneous breaths in all modes. If the interval between ventilator initiated mandatory breaths and breaths detected by the Patient EFFORT Indicator exceeds the chosen delay time (5 - 60 sec for mechanically assisted modes, 10 - 60 sec for Spontaneous mode - adjusted on the front panel behind the door), the alarm activates. This may be caused by patient disconnect, apnea, decreased inspiratory effort of the patient, inappropriate SPONT FLOW setting or inappropriate TRIGGER LEVEL setting.

Make sure that the TRIGGER LEVEL is set so the Patient EFFORT Indicator lights on each patient inspiration. When the alarm is no longer violated, the alarm indicator “latches” (stays lit). Press the ALARM SILENCE Button to cancel “latched” alarm indicators.

Low CPAP Alarm

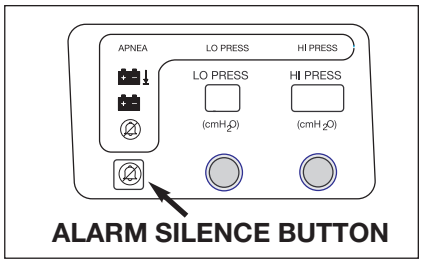


The LOW CPAP ALARM is available in the SPONT MODE only. The APNEA ALARM DELAY knob may be placed in the first position which inactivates the APNEA ALARM and activates the LOW CPAP ALARM. Set the LO PRESS Alarm just below the CPAP level (the LO PRESS Alarm range changes to 0 - 99 cmH_2O instead of 3 - 99 cmH_2O). If the pressure in the circuit as monitored through the proximal pressure sensing port drops below the LO PRESS Alarm setting for 4 seconds, the LO PRESS Alarm sounds.

When the alarm is no longer violated, the alarm indicator “latches” (stays lit). Press the ALARM SILENCE Button to cancel “latched” alarm indicators.

Caution A Low CPAP Alarm setting of < 2 cmH_2O will not detect a disconnect.

Alarm Silence



The ALARM SILENCE Button silences the audible patient related alarms for 60 seconds. The alarm's red indicator light remains flashing until the cause of the alarm condition is corrected. The ALARM SILENCE period (60 sec.) can be cancelled by pushing the Button.

The audible alarm system is automatically reactivated after 60 sec.

You may push the ALARM SILENCE prior to an alarm infraction to pre-silence the alarms prior to suctioning, etc.

Press the Button to cancel "latched" alarm indicators.

Additional Alarms

The following non-patient related alarms cannot be silenced with the Alarm Silence Button.

System Failure

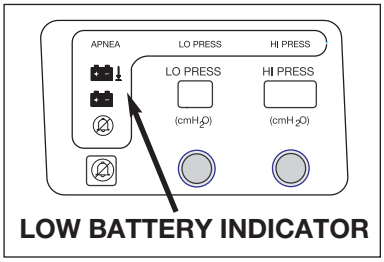
Continuous alarm indicating electrical/mechanical failure.

Air/O_2 Blender

Continuous alarm indicating low inlet gas pressure for either air or oxygen.

Low Battery

Quick pulse alarm indicating battery backup is weak and only approximately 15 minutes of battery power remains. Alternative power supply should be found.



WARNING When the Low Battery alarm sounds an alternative power supply should be found. The alarm indicates only approximately 15 minutes of battery power remains.

6

CLINICAL APPLICATION

The Newport Breeze E150 is designed to ventilate neonates, pediatrics and adults in all patient care areas. Ventilation capabilities include:

- Volume Control Assist/Control + Sigh
- Volume Control Assist/Control
- Volume Control SIMV (with Spontaneous Flow)
- Spontaneous Flow (Spontaneous breathing with or without CPAP) (Vol. & Press.)
- Pressure Control SIMV (with Spontaneous Flow)
- Pressure Control Assist/Control

The Breeze E150 senses airway pressure through a proximal pressure sensing port. In addition to the inspiratory and expiratory limbs, the Breeze E150 patient circuit must have a third (small bore) line connected to the proximal wye connector. This small bore tubing is used to connect the PROXIMAL PRESSURE INLET on the Breeze E150 with the proximal wye connector in the circuit, thereby enabling the Electronic Pressure Gauge and Pressure Display to indicate pressure sensed at the patient's airway.

During mechanical ventilation, mandatory Tidal Volume is a product of selected FLOW (L/min) and INSP TIME (sec.) settings. The set Tidal Volume (V_T) is displayed digitally in the Data Display Panel.

To measure the patient exhaled Tidal Volume, place an uncontaminated respirometer between the patient airway connection and circuit wye.

Volume Control Assist/Control (A/C)

Set-up

1. Assemble ventilator.
2. Connect air and oxygen hoses to the appropriate gas sources.
3. Connect a patient circuit (which includes a proximal sensing line) to the Breeze E150, see pg. 3-2 to 3-4.
4. For heated humidifier or heat moisture exchanger operation, refer to manufacturer's instructions.
5. Plug electrical cord into a properly grounded electrical outlet.
6. Turn the power switch (behind the door on the front panel) to the ON position.
7. Check that all LED indicators light up and then go out after 2 seconds. This ensures proper function of the microprocessor and the LEDs.
8. Attach a test lung to the breathing circuit.
9. Set MODE Selector to A/C.
10. Set patient parameters for F_IO_2, (Respiratory) RATE, V_T (Tidal Volume - use FLOW and INSP TIME).
11. With the HI PRESS Alarm Limit set at 120 cmH_2O, depress the MANUAL Inflation button, observe the Electronic Pressure Gauge, then rotate the blue knurled knob on the Pressure RELIEF VALVE until it is set to pop-off just above the maximum acceptable peak inspiratory pressure.
12. Set a low level, minimum 4 L/min, of SPONT FLOW.
13. Connect the patient to the Breeze E150.
14. Set PEEP slowly. Adjust SPONT FLOW to stabilize the baseline pressure.
15. Adjust the TRIGGER LEVEL just below the PEEP or baseline pressure so that the Patient EFFORT Light comes ON with each spontaneous patient inspiration.
16. Set the HI and LO PRESS Alarms to bracket the average peak inspiratory pressure.
17. Select a delay time for the APNEA Alarm.

Volume Control Assist/Control (A/C)

Theory of Operation

During Assist/Control (A/C) ventilation, a positive pressure breath is delivered with each patient inspiratory effort that causes airway pressure to drop below the TRIGGER LEVEL setting. In Volume Control A/C, tidal volume (V_T) is determined by FLOW and INSP TIME settings. If the patient does not trigger the ventilator, it automatically delivers breaths according to the RATE set. F_IO_2 is selected with the F_IO_2 control (the Air/Oxygen Mixer).

Volume Control Assist/Control (A/C) + Sigh

Set-up & Theory of Operation

Both the Set-up and Theory of Operation for A/C + SIGH are identical to those for A/C, except that with A/C + SIGH, a mechanical "Sigh" breath equal to 1.5 times the preset tidal volume (1.5 times the Inspiratory Time) is delivered to the patient every 100 breaths.

Volume Control SIMV

Set-up

1. Complete steps 1 through 8 under A/C, page 6-2.
2. Select SIMV mode.
3. Adjust the SPONT FLOW to provide flow through the ventilator circuit in between mechanical breaths.
4. Choose the desired F_IO_2, RATE, V_T (Flow and Inspiratory Time).
5. With the HI PRESS Alarm Limit set at 120 cmH_2O, depress the MANUAL Inflation button, observe the Electronic Pressure Gauge, then rotate the blue knurled knob on the Pressure RELIEF VALVE until it is set to pop-off above the maximum acceptable peak inspiratory pressure.
6. Connect the patient to the Breeze E150.
7. Adjust the SPONT FLOW to deliver an adequate amount of gas through the circuit to meet the spontaneous inspiratory demands of the patient and to refill the Reservoir Bag in-between patient inspiratory efforts (See "Spontaneous Flow" on pg. 5-12 for guidelines to setting SPONT FLOW).
8. Slowly set PEEP as needed.

Volume Control SIMV Set-up cont'd

9. Adjust the TRIGGER LEVEL just below the PEEP or baseline pressure so that the Patient EFFORT Light comes ON with each spontaneous patient inspiration.

10. Set the HI PRESS and LO PRESS Alarms to bracket the average peak inspiratory pressure.

11. Select a delay time for the APNEA Alarm.

Volume Control SIMV

Theory of Operation

In SIMV, the patient may breathe spontaneously from the ventilator's spontaneous flow and receive a fixed number of mandatory positive pressure breaths. Tidal volume of the mandatory breaths is determined by the FLOW and INSP TIME setting and is digitally displayed as V_T (Tidal Volume) in the Data Display Panel.

The number of mandatory breaths is controlled by the RATE and synchronized with the patient's breathing pattern with the TRIGGER LEVEL setting. The patient's spontaneous breaths are drawn from the SPONT FLOW through the circuit and Reservoir Bag which has the same F_IO_2 as the mandatory breaths.

NOTE: For more information on SIMV, see section titled SIMV WINDOW, pg. 5-5.

Volume or Pressure Control Spontaneous (SPONT)

There are two SPONT MODES so that the clinician will automatically know how the Breeze E150 will perform when the MANUAL Inflation is used. In the Pressure Control SPONT Mode, the MANUAL Inflation will be pressure controlled at the level of the PIP setting. In the Volume Control SPONT MODE, it will not.

Set up

1. Complete steps 1 through 8 of A/C, pg. 6-2.

2. Select the SPONT MODE.

3. Set F_IO_2.

4. Adjust SPONT FLOW to a minimal level and allow the Reservoir Bag to fill.

5. Connect the patient to the Breeze E150.

Volume or Pressure Control SPONT Set-up cont'd

6. Adjust the SPONT FLOW to deliver an adequate amount of gas through the circuit to meet the spontaneous inspiratory demands of the patient and to refill the Reservoir Bag in-between patient inspiratory efforts (See "Spontaneous Flow" on pg. 5-12 for guidelines to setting SPONT FLOW).

7. Add CPAP if desired.

8. Set TRIGGER LEVEL just below baseline so that the Patient EFFORT Indicator lights with each patient inspiration.

NOTE: If you are having difficulty sensing the patient effort (EFFORT LED not lighting), and the TRIGGER LEVEL is set to the "least amount of effort", you may want to decrease the SPONT FLOW setting. If you see the patient generate significant negative pressure beyond the set TRIGGER LEVEL, you may want to increase the SPONT FLOW setting.

9. Select a delay time for the APNEA alarm or choose the first position, (Low CPAP Alarm) which utilizes the LO PRESS Alarm setting as a disconnect alarm.

10. The Pressure RELIEF VALVE and HI PRESS Alarm should be set as a safety precaution.

NOTE: Although the other parameters are not used in this mode, they should be set in case a manual breath or change to mechanical ventilation is indicated. Depressing the "PRESET" button will cause the digital displays to light up, indicating how each parameter is set.

Volume or Pressure Control Spontaneous (SPONT)

Theory of Operation

In the SPONT MODE, the patient breathes exclusively from the SPONT FLOW moving into the Reservoir Bag and through the patient circuit. The SPONT FLOW should be adjusted to provide the appropriate amount of flow to meet patient spontaneous inspiratory flow demands. All breaths are completely controlled by the patient with respect to RATE, V_T (Tidal Volume) and Peak FLOW. F_IO_2 is set with the F_IO_2 control (the mixer) and if required, CPAP (0-60 cmH_2O) may be added.

The spontaneous breaths are monitored by the Patient EFFORT Indicator and the APNEA alarm when the Apnea Delay is in the 10 - 60 sec. position. The TRIGGER LEVEL must be set properly for the Patient EFFORT Indicator to light, recognizing the patient's spontaneous breaths. The breaths are counted and the total is automatically displayed as TOTAL RATE (Total Rate = a full 60 second count).

When the Low CPAP Alarm is utilized, the SPONT breaths are no longer counted and displayed as TOTAL RATE. Instead, the LO PRESS Alarm display lights up and the LO PRESS Alarm is utilized as a Low CPAP disconnect alarm.

The LO PRESS Alarm should be set just below the CPAP (base) pressure. If the proximal airway pressure drops below the LO PRESS Alarm setting for more than 4 seconds, the alarm will sound.

Caution A Low CPAP Alarm setting of < 2 cmH_2O will not detect a disconnect.

Pressure Control Assist/Control (A/C)

Set-up

1. Assemble ventilator.
2. Connect air and oxygen hoses to the appropriate gas sources.
3. Connect a patient circuit (which includes a proximal sensing line) to the Breeze E150, see pg. 3-2 to 3-4.
4. For heated humidifier or heat moisture exchanger operation, refer to manufacturer's instructions.
5. Plug electrical cord into a properly grounded electrical outlet.
6. Turn the power switch (behind the door on the front panel) to the ON position.
7. Check that all LED indicators light up and then go out after 2 seconds. This ensures proper function of the microprocessor and the LEDs.
8. Attach a test lung to the breathing circuit.
9. Select the PRESSURE CONTROL - A/C MODE.
10. Choose F_IO_2, RATE and INSP TIME.
11. Set SPONT FLOW at min. +4 L/min in order to flush the breathing circuit in between mechanical breaths and stabilize baseline pressure.
12. Set the desired Peak Inspiratory Pressure (PIP) level by adjusting the PIP knob while observing the PEAK Pressure display.
13. Adjust the (mechanical) FLOW to achieve the desired pressure wave pattern.

Pressure Control A/C Set-up cont'd

14. Temporarily place the MODE Selector in the VOLUME CONTROL SPONT MODE. Depress the MANUAL inflation button and while observing the Electronic Pressure Gauge, set the Pressure RELIEF VALVE to pop-off about 5 cmH_2O above the desired PIP level. Make sure the RELIEF VALVE is set above the High Pressure alarm setting. Return the MODE Selector to the PRESSURE CONTROL A/C MODE.

15. Connect the patient to the ventilator.

16. Slowly adjust PEEP as needed. Readjust SPONT FLOW to guarantee a stable baseline.

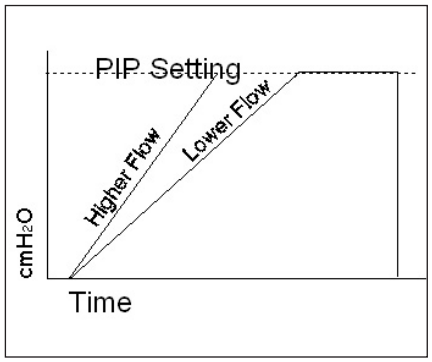
17. The TRIGGER LEVEL should be set just below baseline pressure.

18. Set the LO PRESS Alarm 1-2 cmH_2O below the Peak Inspiratory Pressure (PIP). Set the HI PRESS Alarm 2-3 cmH_2O above the PIP.

19. Select a delay time for the APNEA alarm.

Pressure Control Assist/Control (A/C)

Theory of Operation



Although much like the standard ventilatory pattern of Volume Control Assist/Control (A/C), this mode differs in that each breath is limited at a particular peak pressure. Instead of each breath being volume limited and pressure variable, it is pressure limited and volume variable. This type of ventilation provides a descending ramp flow pattern.

When the Peak Inspiratory Pressure set by the PIP knob is reached, a pressure plateau results for the duration of the Inspiratory Time. The size of the mandatory inspiration is determined by the difference in pressure between the PEEP level and the PIP level, and shape of the pressure waveform created by the (mechanical) FLOW and INSP TIME settings.

The volume delivered during the plateau time varies, depending on changes in patient/system resistance, compliance, and leaks around the artificial airway.

This mode may be used for full ventilatory support of any patient when you wish to maximize oxygenation and at the same time, control the peak ventilating pressure.

Pressure Control SIMV

Set-up

1. Complete steps 1 through 8 of A/C, pg. 6-2.
2. Select PRESSURE CONTROL SIMV MODE.
3. Choose F_IO_2, RATE, and INSP TIME.
4. The SPONT FLOW should be turned ON to provide mixed gas flow through the breathing circuit for spontaneous breathing in-between mechanical breaths.
5. Adjust the PIP (Peak Inspiratory Pressure) while observing the Electronic Pressure Gauge.
6. Adjust the (mechanical) FLOW to achieve the desired pressure wave pattern.
7. Temporarily place the MODE Selector in the VOLUME CONTROL SPONT MODE. Depress the MANUAL Inflation Button and while observing the Electronic Pressure Gauge, set the Pressure RELIEF VALVE to pop-off about 5 cmH_2O above the PIP level. Make sure the RELIEF VALVE is set above the High Pressure Alarm setting. Return the MODE Selector to the PRESSURE CONTROL SIMV MODE.
8. Connect the patient to the ventilator.
9. Slowly adjust PEEP as needed.
10. The TRIGGER LEVEL should be set just below baseline pressure.

NOTE: The Patient EFFORT Indicator may not light with patient effort if airway pressure does not drop below the TRIGGER LEVEL setting. This may occur if the patient's effort is inadequate, SPONT FLOW is set too high, or there is a significant leak around the endotracheal tube. In the case where patient effort is less than .1 cmH_2O, you may replace the Reservoir Bag with the Reservoir Bag Cap to improve the patient's ability to trigger. See instructions on pg. 4-1 for use of the Reservoir Bag Cap.

11. Set the LO PRESS Alarm 1-2 cmH_2O below the Peak Inspiratory Pressure (PIP). Set the HI PRESS Alarm 2-3 cmH_2O above the Peak Inspiratory Pressure (PIP).
12. Adjust the SPONT FLOW to deliver an adequate amount of gas through the circuit to meet the spontaneous inspiratory demands of the patient and to refill the Reservoir Bag in-between patient spontaneous breaths (See "Spontaneous Flow" on pg. 5-12 for guidelines on setting SPONT FLOW).
13. Select a delay time for the APNEA Alarm.

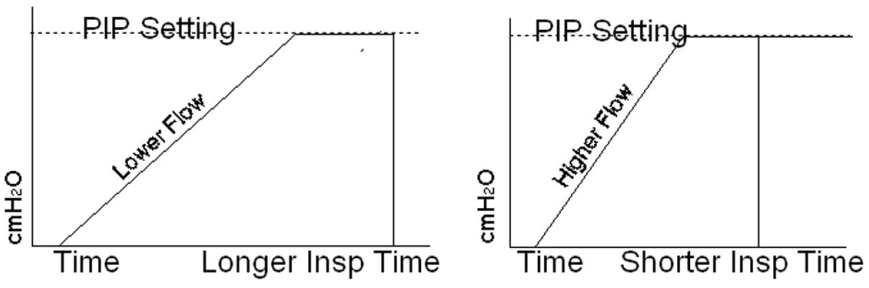
Pressure Control SIMV

Theory Of Operation

Primarily, this mode is used for neonatal/pediatric ventilation. Although the ventilatory cycle is much like that of VOLUME CONTROL SIMV Ventilation, this mode differs in that each breath is limited at a particular peak pressure by the Peak Inspiratory Pressure mechanism (PIP control). Instead of each breath being volume limited and pressure variable, it is pressure limited and volume variable. This type of ventilation provides a descending ramp flow pattern.

PRESSURE CONTROL SIMV Ventilation combines a mandatory rate with patient spontaneous breathing. The number of mandatory breaths is determined by the RATE control and synchronized with the patient's breathing pattern with the TRIGGER LEVEL setting. The patient's spontaneous breaths are drawn from the SPONT FLOW through the circuit and Reservoir Bag. SPONT FLOW has the same F_IO_2 as the mandatory breaths. During a mandatory breath the (mechanical) FLOW setting determines the maximum flow delivered to the patient. The INSP TIME control determines how long the mechanical flow will be delivered and the PIP control determines the maximum pressure that can be achieved during the mechanical breath.

The (mechanical) FLOW controls flow and therefore the pressure wave pattern for each mandatory breath. All spontaneous breaths are taken from SPONT FLOW which is adjusted separately with the SPONT FLOW knob to meet the spontaneous inspiratory flow demands.



Pressure Control Ventilation: Vary Mechanical Flow and Insp Time to change waveform.

NOTE: For more information on SIMV, see section titled SIMV WINDOW, pg. 5-5.

7

WARNINGS/PRECAUTIONS

The following warnings and precautions are guidelines to assist the clinician in the safest possible operation of the Newport Breeze E150 ventilator.

General

Always observe, monitor and clinically evaluate patients while they are receiving mechanical ventilation.

Periodically measure, by using a calibrated oxygen analyzer, the accuracy of the selected oxygen concentration.

Make sure that the Reservoir Bag refills itself between each breath during spontaneous breathing in the SPONT and SIMV Modes. Adjust the SPONT FLOW to prevent the bag from depleting.

Always check ventilator performance before connection to the patient.

Always wash hands before and after touching the patient, breathing circuit, or using the ventilator.

Before patient application, perform a “leak test” on the Breeze E150 ventilator, breathing circuit, and humidifier. See Section 10, Quick Check Procedure.

Caution Federal (USA) law restricts the sale of this device to, or on the order of, a physician.

WARNING TO PREVENT EXPLOSION HAZARDS IN THE PRESENCE OF OXYGEN, DO NOT USE ANY INSTRUMENTS OR OTHER EQUIPMENT CONTAMINATED WITH OIL OR GREASE. OXYGEN VIGOROUSLY SUPPORTS COMBUSTION.

DO NOT USE THE BREEZE E150 VENTILATOR IN THE PRESENCE OF FLAMMABLE ANESTHETICS AS A POSSIBLE EXPLOSION HAZARD EXISTS.

Warnings/Precautions

A.C. Power Source

Always insert the hospital grade electric power cord into the correct voltage and properly grounded receptacle.

Always use a 1 Ampere, 250 V fuse (for 100-120 Volt) or .5 Ampere, 250 V fuse (for 220-240 Volt) to replace a blown one. If this problem occurs frequently, contact a factory authorized representative.

Gas Supply Sources

Ensure that the air and oxygen supply source pressure lines are connected to their appropriate DISS fittings on the Air/Oxygen Mixer.

Ensure that both supply source gases are, and remain, dry and clean.

Ensure that both supply source pressures are 50 psig (90 psig maximum, 35 psig minimum) or 2.45 Kg/cm^2 - 6.3 Kg/cm^2.

Keep the Air/Oxygen Mixer bleed hole free from obstruction so that the mixer alarm function will not be impaired.

Periodically check, and if necessary, drain water from the air inlet water trap bowl to prevent Air/Oxygen Mixer contamination.

When oxygen and/or air cylinders are used as a supply source, ensure that spare cylinders are available.

Be aware of the internal resistance of circuits and humidifiers. The spontaneously breathing patient must overcome this pressure in order to open the Emergency Intake Valve in the event of a total gas supply source failure.

In the case of an inlet gas failure, provide an alternate source of ventilation until the gas pressure is restored.

Breathing Circuits/Humidifiers

Always use a clean or sterile breathing circuit.

Periodically drain the patient breathing circuit to prevent water accumulation which can harm the patient, distort waveforms, increase circuit resistance to inspiration or exhalation, and possibly cultivate pathogenic organisms.

Either place a heated humidifier filled with sterile water in-line with the patient circuit or place a heat-moisture exchanger in-line at the proximal airway. Never deliver a dry, unheated gas.

Breathing Circuits/Humidifiers

Follow the operating and cleaning instructions in the Manufacturer's Operation Manual for the heated humidifier.

Monitor the water level in the heated humidifier chamber or solution in the nebulizer cup.

Contamination possibilities can be reduced by installing bacterial filters between the mainflow outlet and the patient breathing circuit and between the nebulizer outlet and the nebulizer.

A hydrophobic filter should be used in the Proximal Pressure Sensing Line between the ventilator and the patient to prevent organisms or water from contaminating the Electronic Pressure Gauge.

When nebulizing substances in-line with the patient circuit, use a filter between the expiratory limb of the patient breathing circuit and the Exhalation Valve to protect the valve from contamination. The filter should be checked for resistance and changed regularly to protect the patient from possible expiratory resistance as a result of a clogged filter.

Ethylene oxide is toxic. All components must be completely dry prior to packaging for sterilization. After sterilization is completed, properly aerate to dissipate residual gas absorbed by the material. Follow the sterilizer manufacturer's recommendations for the specific aeration periods required.

Use NMI approved patient breathing circuits. If a proximal pressure sensing line is being used, it must be either 1/8" or 3/16" i.d. for proper performance and monitoring.

Ventilator

To protect the patient from accidental exposure to high pressure, adjust the Pressure Relief Valve 2 - 3 cmH_2O higher than the High Pressure Alarm limit.

The ventilator functions only when the power switch is in the ON position, with the A.C. power cord inserted into the proper receptacle or if the internal battery is in use.

Use a soft cloth moistened with a mild, medically-safe detergent solution to wipe off the ventilator. DO NOT gas sterilize or autoclave the Breeze E150. Do not use paper products to wipe off the face panel.

A Breeze E150 ventilator which does not meet manufacturer's design specifications should not be used until all necessary repairs have been made.

Ventilator

All service and repair of the Breeze E150 ventilator should be done by authorized NMI factory trained service personnel.

Do not operate the Breeze E150 ventilator with the case open. Electrical shock hazard may be encountered.

When the Breeze E150 ventilator is connected to a patient, constant attention by a qualified medical attendant is required.

Prompt attention should be given to every alarm. Some alarm conditions require immediate corrective action.

The Alarm Silence Button  on the Breeze E150 ventilator should not be used until the cause of the alarm has been determined, and patient safety is determined not to be at risk.

Only an NMI permanent exhalation valve should be used in conjunction with the Breeze E150 ventilator.

Audible Visual Alarm Systems

The ventilator and audible/visual alarm systems can only function when the ventilator power switch is in the ON position.

Whenever a patient is connected to a ventilator, qualified personnel should be in the area at all times. The use of a ventilator with incorporated alarm systems or additional alarm systems does not give absolute assurance of warning for every type of ventilator, breathing circuit, or patient system malfunction.

Certain clinical as well as technical problems require immediate action.

Pressure Relief Valve

In all modes of ventilation, set the RELIEF VALVE above the HI PRESS Alarm setting as a secondary safety mechanism.

Face Panel Controls

After servicing the ventilator with the face panel removed, make sure to follow procedures outlined in the Service Manual for calibration and adjustment of control knobs.

8

STERILIZATION/DECONTAMINATION

The Newport Breeze E150 Ventilator and the associated patient circuit are shipped in a clean but not sterile condition. After each use, or more often if necessary, it is important to clean the exterior surface of the ventilator and the entire patient circuitry.

Patient Circuit

Detach the patient circuit, exhalation valve and humidifier chamber from the ventilator and disassemble to expose all surfaces.

Thoroughly wash all equipment to be sterilized or disinfected to remove secretions and other residue.

Clean the patient circuit components in a medical detergent solution and thoroughly flush, preferably with distilled water.

Sterilize patient circuit components using liquid chemicals, pasteurization, steam autoclave or ethylene oxide. Use liquid chemical agents according to the manufacturer's recommendations. Be sure that the agent is compatible with plastics and anodized aluminum.

NOTE: Ethylene oxide may cause superficial crazing of plastic components and will accelerate the aging of rubber components.

Caution ETHYLENE OXIDE IS TOXIC. All components MUST be completely dry prior to packaging for ethylene oxide sterilization. After sterilization, they must be properly aerated to dissipate residual gas absorbed by the material. Follow the sterilizer manufacturer's recommendations for the specific aeration periods required.

Sterilization/ Decontamination

Ventilator/Stand-Pole Assembly

The exterior of these surfaces may be wiped clean with a soft cloth which has been moistened with a medically appropriate germicidal agent.

NOTE: Do not allow any liquid to enter the ventilator housing, electrical, or signal ports.

Do not spray aerosolized agents on the Breeze E150 face panel or housing.

Do not allow the face panel or ventilator housing to come in contact with agents that contain acetone, toluene, halogenated hydrocarbons or strong alkalines.

Do not use paper products to clean the Breeze E150 face panel.

The Breeze E150 is NOT AUTOCLAVABLE!

General Guidelines

Only sterile fluids should be nebulized or used in a humidifier and they should be dispensed aseptically. Contaminated equipment should not be allowed to touch the fluid while it is being dispensed. Water that has precipitated in the tubing should be discarded and not allowed to drain back into the humidifier chamber.

Routinely change the breathing circuit (including patient circuit tubing, exhalation valve, nebulizer, high volume humidifier) and replace with a sterile or disinfected replacement every 24-48 hours, or as required by hospital protocol.

Respirometers used to monitor several patients in succession should not directly touch parts of the breathing circuit. Extension pieces (adapters) and bacteria filters should be used between the spirometer and the breathing circuit and should be changed between patients.

9

MAINTENANCE/TROUBLESHOOTING

Preventative Maintenance

To ensure patient safety, NMI recommends that you visually inspect the Breeze E150 and perform the Quick Check Procedure (see Section 10) prior to each time it is placed into service on a patient. The Operational Verification and Calibration Procedure (see Service Manual) is performed with the annual Preventative Manintenance. The OVP should also be performed according to hospital policy or any time the ventilator has been serviced. Preventative Maintenance should be completed after every 3,000 hours of operation (or earlier if the Breeze E150 fails to pass the Quick Check Procedure), or a minimum of once each year. The Preventative Maintenance is intended to be done in the hospital.

Preventative Maintenance Includes:

- Visually inspect the external surfaces, controls, attachments and accessories.
- Replace the Air and Oxygen mixer inlet filters (part # MFK110A).
- Clean the air inlet Water Trap and replace the Jar Filter (JFK100P).
- Remove the top cover and visually inspect the interior, all tubing, wires and wiring connectors, screws, nuts, and hardware, checking the general condition of all components.
- Perform Operational Verification on the Breeze E150 and recalibrate if necessary.

Overhaul

The Breeze E150 should be overhauled every 5 years or 15,000 hours of operation. The Overhaul must be performed by a Newport Medical service technician at the NMI factory service center. In addition to the items performed during Preventative Maintenance, an Overhaul includes the overhaul of the Air/O_2 mixer and replacement of moving parts as required. Contact NMI Service Department for further information on the above service @ 714.642.3910 or 800.451.3111, ext. 500.

Recommended Spare Parts

Reservoir Bag		BAG121P	2 each
Pressure Relief Valve (pop-off)		POP120A	1 each
Diaphragm		DIA200P	2 each
Jar Filter Kit		JFK100P	2 each
Mixer Filter Kit		MFK110A	2 each
Fuses			
110 V/120 V Operation	1 Amp.	FUS200P	2 each
220 V/240 V Operation	.05 Amp.	FUS050P	2 each
Fuse for power PCB (Inside Vent)	3 Amp.	FUS300P	2 each

Clinical Troubleshooting

It is important that both the clinician and biomedical service people have a thorough understanding of the Newport Breeze Model E150 Ventilator pneumatic/electronic systems.

Supporting the moral obligations of every involved professional to have a working understanding of the equipment as used in life-support situations, the following practical troubleshooting guidelines are provided. It should be noted that this outline is not all-inclusive and is only intended as a guide.

Further questions or problems should be addressed to the Customer Service Department of Newport Medical Instruments 714.642.3910 or 800.451.3111, ext. 282.
FAX 714.548.3091. Or you may write to:

Customer Service Department
NEWPORT MEDICAL INSTRUMENTS, INC.
Post Office Box 2600
Newport Beach, CA 92658 USA

Newport Breeze E150 Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	REMEDY
OXYGEN CONCENTRATION Delivered O_2 concentration varies more than 3% from selected concentration (Gas sources 40 - 60 psig).	O_2 analyzer not correctly calibrated. Mixer contaminated with condensate. Mixer knob has slipped.	Calibrate according to Manufacturer's Operation Manual. Call factory authorized representative Calibrate mixer knob.
SELF TEST All lights on front panel remain ON longer than 2 seconds.	Problem with microprocessor board.	Contact NMI service center.
ALARMS Air/Oxygen mixer alarms.	Air and/or Oxygen supply source difficulties. Inlet gas pressures are not between 35 and 90 psig.	Plug Air and O_2 supply lines in at exactly the same time or in reverse order. If using gas cylinders, ensure that both are full, valves turned fully OPEN and operating pressures are between 35 and 90 psig. Ensure hose fittings are correctly inserted into hospital wall outlets. Check all of the above and that inlet gas is dry. If using an air compressor, ensure A.C. power cord is plugged in and switch is in the ON position and operating in the green range.

Newport Breeze E150 Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	REMEDY
ALARMS		
Mixer does not alarm with only one gas source being connected.	Bleedhole obstructed.	Remove obstruction.
	Dirty inlet filters.	Replace filters.
	Alarm reed broken or damaged.	Replace reed.
	Condensate in mixer.	Call factory authorized representative.
	Leaking check valve.	Call factory authorized representative.
A.C. POWER FAILURE ALARM		
Continuous alarm sound.	Ventilator electric power cord accidentally disconnected and the internal battery is non-functional.	Reinsert plug.
	Hospital electric circuit failure and the internal battery is non-functional.	Ventilate patient manually until problem is corrected or replace the Breeze E150 with pneumatically powered and operated ventilator.
Alarm does not sound during an electric disconnect or power failure.	The Breeze E150 has switched over to the internal battery for 1 hour.	Prepare for hand ventilation after one hour of battery operation or replace with pneumatically powered and operated ventilator.
	Ventilator ON/OFF switch is in OFF position.	Switch ON.
ALARM SILENCE		
Standard operating alarms are not silenced when Alarm Silence button is pressed.	Alarm silence button is damaged.	Call factory authorized representative.

Newport Breeze E150 Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	REMEDY
HIGH PRESSURE ALARM	Increased patient and/or breathing circuit resistance which causes an increase in ventilating pressure, exceeding the set high alarm limits.	Evaluate patient and remedy any mechanical problems.
	High pressure sensor was not adjusted for PEEP.	Adjust indicator position a minimum of 2-3 cmH_2O above peak inspiratory pressure.
LOW PRESSURE ALARM	Leak in breathing circuit and/or patient artificial airway (cuff, etc.).	Correct leak.
	Inlet gas supply pressure loss.	Reestablish gas supply sources. Ventilate manually until pressure is restored.
APNEA ALARM	No spontaneous breath detected in the time set on delay time control due to changes in patient status, i.e., decreased respiratory rate or inspiratory effort.	Evaluate patient breathing rate and effort and evaluate appropriateness of ventilator settings.
	Improper delay time or trigger level setting.	Reassess delay time and trigger level settings.
	Leak in patient circuit/disconnect.	Correct leak.
	Patient effort is small and reservoir bag is in place.	Replace reservoir bag with reservoir bag cap.
	Patient effort is small and reservoir bag cap is in place.	Use LOW CPAP Alarm (SPONT mode only) instead of Apnea Alarm. Monitor for Apnea with alternate device.

Newport Breeze E150 Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	REMEDY
MECHANICAL/ SPONTANEOUS VENTILATION		
Reservoir bag depletes during spontaneous inhalation.	Patient inspiratory flowrate demand is not met by SPONT FLOW setting.	Adjust SPONT FLOW so reservoir bag stays full during respiratory cycle.
	Leak in the breathing circuit.	Correct leak.
	Reservoir bag with bleed valve is in place.	Replace with reservoir bag without bleed valve.
Desired machine tidal volume is not delivered during the selected inspiratory time.	Leak in breathing assembly system.	Correct Leak.
	Pressure relief valve setting is too low. Volume is vented when relief valve setting is reached.	Readjust relief valve 3-5 cmH_2O above the High Pressure Alarm setting.
PEEP/CPAP pressure does not meet maximum pressure specifications with the PEEP/CPAP control in the fully OPEN (counterclockwise) position.	Leak in breathing circuit.	Correct leak.
	Pressure relief valve is set lower than CPAP pressure.	Increase pressure relief valve setting by rotating clockwise.
	Faulty exhalation valve or exhalation valve diaphram.	Check and replace as needed.
	Leaking PEEP/CPAP control valve assembly.	Call factory authorized representative.
Ventilator self triggers.	TRIGGER LEVEL indicator not set properly.	Adjust indicator position just below baseline pressure.
	Leak in breathing circuit.	Correct Leak.

Newport Breeze E150 Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	REMEDY
MECH/SPONT VENTILATION		
Ventilator does not respond to patient inspiratory effort.	Patient effort too weak.	Cap off Reservoir Bag Outlet.
	Incorrect TRIGGER LEVEL indicator position. Airway pressure does not drop below indicator position.	Readjust TRIGGER LEVEL indicator position.
	Leak in breathing circuit.	Correct leak in breathing circuit.
Low and/or High Pressure Alarms are activated.	Leak in breathing circuit.	Correct leak in breathing circuit.
	Breathing circuit or proxline occlusion.	Look for occlusion and fix it.
	Electronic malfunction.	Call factory authorized representative.
Ventilator does not function in any mode.	A.C. power cord not plugged in and internal battery is depleted.	Plug into approved A.C. receptacle.
	ON/OFF switch in OFF position.	Switch to ON.
Ventilator stops cycling.	Blown fuse and internal battery power supply is depleted.	Replace with fuse of same type and rating.
	Electronic malfunction.	Call factory authorized representative.
	Inlet supply gas source failure.	Re-establish functional system; correct inlet gas pressures to 35 - 90 psig.
PEEP/CPAP APPLICATION		
Airway pressure dips below selected PEEP/CPAP pressure first, prior to stabilizing.	Faulty exhalation valve diaphram.	Check and replace as necessary.
	In SIMV or SPONT modes, SPONT FLOW L/min selection does not meet patient inspiratory flowrate demand.	Adjust SPONT FLOW to prevent bag from depleting during inhalation.

Newport Breeze E150 Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	REMEDY
PEEP/CPAP APPLICATION		
With PEEP/CPAP control fully closed, positive pressure is still displayed on pressure gauge after patient exhalation.	Resistance to exhalation in patient breathing circuit.	Change exhalation valve or entire breathing circuit.
	SPONT FLOW set too high.	Re-adjust SPONT FLOW.
	Inadequate expiratory time.	Evaluate RATE and INSP TIME settings.
	Pressure manometer out of calibration.	Contact NMI Service center.
	Leaking PEEP/CPAP control valve assembly.	Contact NMI Service center.
	Intubation tube (size, etc.) is too small causing expiratory resistance.	Re-intubate with larger ET tube.
MANUAL INFLATION		
Cannot generate sufficient pressure/insufficient chest expansion.	Pressure RELIEF VALVE setting too low.	Adjust RELIEF VALVE pressure as required.
	Gross leak.	Correct leak and check pressure.
Pressure builds up too slowly.	Leak in breathing circuit.	Correct leak and recheck pressure.
	FLOW setting too low.	Increase as required.
Pressure builds up too fast.	FLOW setting too high.	Decrease as required.
High Pressure Alarm is activated during manual inflation.	Inflation pressure exceeds ventilator High Pressure limit.	Stop pressing MANUAL before pressure rises to High Pressure limit.

10

QUICK CHECK PROCEDURE

PURPOSE

This procedure is intended to assist a qualified operator establish a routine verification program to ensure proper operation of the Newport E150 Breeze ventilator. You should perform this Quick Check each time the ventilator is prepared for clinical use.

Do not use the ventilator if it does not pass the Quick Check Procedure.

1. Pre-Test Inspection

Verify that the condition of the A.C. power cords for the ventilator and the NMI air compressor (if used) are in good working condition, then connect them to an A.C. wall receptacle.

Inspect the water trap connected to the air supply hose. Remove any water or debris that has accumulated in the bottom of the water jar, then connect the air and oxygen supply lines from the ventilator to the appropriate wall gas outlets. Gas outlet pressure must be50 $\pm$ 10 psig.

Connect an adult breathing circuit w/ proximal pressure sensing line ($^1/8$”) and an adult test lung (NMI #LNG600P or equivalent) to the ventilator. Examine the test lung and patient breathing circuit to ensure there is no degrading of the material which would cause “leaks”.

2. Loss of Gas Alarm

Disconnect the oxygen supply. Verify that the air/oxygen mixer alarm is violated. Reconnect the oxygen supply. Verify that the alarm is silenced.

Disconnect the air supply. Verify that the air/oxygen mixer alarm is violated. Reconnect the air supply. Verify that the alarm is silenced.

3. Power-Up Self-Tests

Press the power switch located on the front panel of the NMI air compressor (if used) to the “ON” position. Verify that the “Low Pressure” alarm sounds and, if using the C200 air compressor, that the alarm indicator is “lit”.

Verify that after sufficient time (less than 30 sec.) the needle on the pressure gauge on the compressor is in the “green”, and that the Low Pressure alarm is no longer violated.

Press the power switch located behind the lower front panel of the E150 Breeze ventilator to the “ON” position. Verify that all indicators and displays “light” and the audible alarm sounds.

4. Leak Check

Set the MODE control to either SPONT position.

Set the SPONT FLOW to 6 L/min.

Rotate the PEEP knob until the pressure gauge shows approx. 30 cmH_2O.

While watching the pressure gauge, turn the SPONT FLOW control fully counter clockwise (min). Airway pressure should not drop more than 5 cmH_2O in 5 seconds.

Turn the PEEP/CPAP off by rotating the PEEP/CPAP control fully counter-clockwise.

5. Pressure Gauge Check

Disconnect the test lung from the circuit wye connector.

Verify that the pressure gauge is showing 0 cmH_2O.

Reconnect the test lung.

6. Operational Check (Volume Control)

Set the RATE control to 30 b/min, the INSP TIME control to 1.00, the FLOW control to 24 L/min, and the MODE control to the VOLUME CONTROL SIMV position.

Verify that the ventilator is cycling and delivering positive pressure breaths.

Verify that after 1 minute the TOTAL RATE display shows 30 ($\pm$ 1 b/min).

6. Operational Check (Volume Control) cont'd.

Verify that the I:E display shows 1:1.0 (± .1)

Verify that the V_T display shows .40 (± .04 L)

7. Operational Check (Pressure Control)

Set the MODE control to the PRESSURE CONTROL SIMV position.

Increase the FLOW control to 40 L/min.

Press the BASE button and verify that the PRESSURE Display shows 0 cmH_2O.

Press the PEAK button. While monitoring the PRESSURE Display, rotate the PIP knob until 20 cmH_2O is displayed.

Looking at the pressure gauge, verify that an inspiratory pressure plateau occurs at 20 cmH_2O (± 2 cmH_2O).

8. PEEP/CPAP Check

Make certain that the Reservoir Bag or the blue Reservoir Cap is attached to the reservoir outlet, located at the bottom right corner of the ventilator.

Press the BASE button. Verify that the PRESSURE Display shows 0 cmH_2O.

Rotate the PEEP/CPAP control until the PRESSURE Display shows 5 cmH_2O.

Verify that the pressure gauge shows 5 cmH_2O (± 2 cmH_2O).

9. Pressure Alarms Check & Alarm Silence Button

Press the PEAK button, noting the pressure shown in the PRESSURE Display. Rotate the HI PRESS alarm control counter-clockwise until the alarm display is 5 cmH_2O below the PEAK pressure reading. Verify that the HI PRESS alarm is violated (audible & visual).

Rotate the HI PRESS alarm knob to adjust the high pressure alarm setting 5 cmH_2O above the peak pressure. Verify that the HI PRESS alarm is no longer violated.

9. Pressure Alarms Check & Alarm Silence Button cont'd.

Rotate the LO PRESS alarm control clockwise to adjust the low pressure alarm 5 cmH_2O above the peak pressure. Verify that the LO PRESS alarm is violated (audible & visual).

Press the button. Verify that the LO PRESS alarm indicator continues to "blink", but that the audible alarm is silenced.

Rotate the LO PRESS alarm control to readjust the low pressure alarm setting to 5 cmH_2O below the peak pressure. Verify that the LO PRESS alarm is no longer violated.

Press the button. Verify that the "latched" alarm indicators are cancelled.

10. TRIGGER LEVEL Check

Set the MODE control to PRESSURE CONTROL A/C.

Set the RATE control to 1 b/min.

Rotate the TRIGGER LEVEL control until the trigger level indicator on the pressure gauge is 1 cmH_2O below the baseline.

Squeeze the test lung lightly and release, creating a negative pressure.

Verify that the EFFORT indicator "blinks" and that a mandatory positive pressure breath is delivered.

11. APNEA Alarm Check

Set the APNEA TIME control (located behind the lower front panel) to 30 seconds. Set the MODE control to SPONT (Pressure or Volume).

Press the MANUAL breath button. Verify that after approx. 30 seconds the APNEA alarm is violated (audible & visual).

12. Internal Battery Check

Set the MODE control to PRESSURE CONTROL A/C. Set the RATE to 15 b/min.

While the ventilator is cycling, unplug the A.C. power cord from the wall outlet. Verify that the Battery in Use indicator "lights", and that the audible alarm for the battery switchover activates briefly (approx. 2 seconds).

Verify that the ventilator continues normal operation.
Plug the A.C. power cord into the wall outlet. Verify that the Battery in Use indicator is no longer "lit".

13. MODE Control Check

Rotate the MODE control fully clockwise. Verify that the position indicator on the control knob is aligned with the A/C position.

Rotate the MODE control fully counter-clockwise. Verify that the position indicator on the control knob is aligned with the A/C + SIGH position.

14. F_IO_2 Accuracy Check

Adjust the SPONT FLOW control to 10 L/min.

Place a *calibrated* oxygen analyzer inline with the patient breathing circuit.

Adjust the F_IO_2 Control to 60%. Verify that the oxygen analyzer displays 60% $\pm$ 3 O2 %.

15. Proximal Line Purge Flow Test

Occlude the proximal pressure line. Verify that the pressure gauge displays 30 - 60 cmH_2O. Release the line.

16. Power Down Alarm

Switch power off to the ventilator. Verify that a continuous audible alarm activates (no visual).

Press the  button. Verify that the power down alarm is silenced.

17. Emergency Intake Valve

Disconnect the air and oxygen supplies.

Verify that air can be pulled through the emergency intake valve by creating a negative effort on the inspiratory limb of the breathing circuit. This can be done (1) with a “bellows” type test lung, or (2) by inspiring through the inspiratory limb of the patient circuit.

Newport Medical Instruments strongly recommends that before breathing through a patient circuit, you should take care to ensure the circuit is clean and sterile and that a clean and sterile bacteria filter is first placed on the circuit wye connector.

This concludes the Quick Check Procedure.

Newport MEDICAL

Breeze E150 Ventilator QUICK CHECK
Pass/Fail Check Off Sheet

Preparation for Pre-Use Tests		Indicate status for each test	
1.	Pre-test Inspection	Pass ____	Fail ____
2.	Loss of Gas Alarm	Pass ____	Fail ____
3.	Power Up Self-Test	Pass ____	Fail ____
4.	Leak Check	Pass ____	Fail ____
5.	Pressure Gauge	Pass ____	Fail ____
6.	Operational Check (Volume Control)	Pass ____	Fail ____
7.	Operational Check (Pressure Control)	Pass ____	Fail ____
8.	PEEP/CPAP	Pass ____	Fail ____
9.	Pressure Alarms & Alarm Silence Button	Pass ____	Fail ____
10.	Trigger Level	Pass ____	Fail ____
11.	Apnea Alarm	Pass ____	Fail ____
12.	Internal Battery	Pass ____	Fail ____
13.	Mode Control	Pass ____	Fail ____
14.	F_IO_2 Accuracy	Pass ____	Fail ____
15.	Proximal Line Purge Flow	Pass ____	Fail ____
16.	Power Down Alarm	Pass ____	Fail ____
17.	Emergency Intake Valve	Pass ____	Fail ____

The ventilator is ready for operation when all tests have been performed successfully.

Note any comments on inspection of unit, corrective action taken, or recommendations for further action.

_____

_____

_____

Completed by: _____ **Date:** _____

Facility: _____ **Serial #** _____ **Unit hours** _____

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WARRANTY

Newport Medical Instruments, Inc. (NMI) warrants this product to meet the published specifications and to be free from defects in material and workmanship under normal use for a period of one (1) year from date of purchase. The foregoing is in lieu of any other warranty, expressed, implied or statutory, including without limitation any warranty or machinability, warranty of fitness for any particular purpose, or warranty of any kind as to design. The sole liability of NMI under this warranty is limited to replacing, repairing or issuing credit at the discretion of NMI for the products, equipment or parts which fail to meet the published specifications or which become defective during warranty period and which are, upon examination by NMI, found not to meet the published specifications or to be defective in materials or workmanship.

NMI will not be liable under this warranty unless the following provisions are strictly complied with. (a) NMI is promptly notified, in writing, upon discovery of the failure of the said product or equipment to meet the published specifications or of the defects in materials or workmanship. (b) The defective product, equipment or part thereof is returned to NMI, transportation charges to be paid by NMI. (c) The defective part is received by NMI for examination no later than one (1) month following the expiration of the warranty period and provided (d) that examination by NMI of said product, equipment or part shall disclose to NMI's satisfaction that such defect has not been caused by improper usage, accident, neglect, alteration, abuse, improper installation or unauthorized repair. Products, equipment or parts replaced under this warranty are warranted only through the terms of the original warranty.

NMI neither assumes nor authorizes any other person or entity to assume for it any other warranty, obligation or liability in connection with its products or equipment whatsoever, and as to the fitness or usefulness of the equipment manufactured by it for any medical treatment, physical condition or other purpose whatsoever. In no event shall NMI be liable for personal injury, property damage or any special or consequential damage to the buyer, user or any other person whomsoever, including, but not limited to, loss of profits, loss of use of the product or equipment, or for damages of any kind whatsoever based on a claim for breach of warranty other than a refund of the purchase price of any defective product or equipment. Any authorization for repair or alteration by buyer must be in writing from NMI to prevent the voiding of this warranty.